From: Wholley, David (FNIH) [T]
Sent: Tue, 11 Oct 2016 16:49:41 -0400
To: Collins, Francis (NIH/OD) [E]
Cc: Smith, Philip (NIH/NIDDK) [E];Whitaker, Sanya (FNIH) [T];Spear, Nicole (FNIH) [T]
Subject: FW: Departure

Francis,
Please see below. (b) (5)
David

From: Whitaker, Sanya (FNIH) [T]
Sent: Tuesday, October 11, 2016 3:25 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: FW: Departure

fyi

From: Whitaker, Sanya (FNIH) [T]
Sent: Tuesday, October 11, 2016 3:24 PM
To: 'Stein, Peter Paris' <peter.stein@merck.com>; Spear, Nicole (FNIH) [T] <nspear@fnih.org>
Subject: RE: Departure

Hi Peter,

We very much appreciate your time with us as co-chair and it has been great to be able to work with you. The Steering Committee has made tremendous progress under your and Phil's leadership. Hopefully, we will have the opportunity to work with you again sometime in the future.

Best of luck in your new endeavors.

Kind Regards,

Sanya and Nicole

Sanya Fanous Whitaker, PhD, PMP
Scientific Program Manager – Metabolic Disorders
Division of Research Partnerships
Foundation for the National Institutes of Health

9650 Rockville Pike | Bethesda, MD 20814 | www.fnih.org
Direct (301) 496-1518 | Mobile (b) (6) | swhitaker@fnih.org

FNIH
Foundation for the National Institutes of Health

For eleven consecutive years, Charity Navigator has rated the FNIH as an organization that exceeds industry standards.

From: Stein, Peter Paris [mailto:peter.stein@merck.com]
Sent: Tuesday, October 11, 2016 3:17 PM
To: Whitaker, Sanya (FNIH) [T] <swhitaker@fnih.org>; Spear, Nicole (FNIH) [T] <nspear@fnih.org>
Subject: Departure

Hi Sanya, Nicole,

As I indicated to you recently, I am leaving Merck – and my role on the SC for AMP/T2DM. It has truly been a pleasure working on this project – and learning from the SC members and you both.

This is my last week at Merck – and I likely will not be able to call in on Friday.

I have asked Roger Perlmutter to assign a replacement, which, as yet, he has not done. Hopefully, another SC representative from Merck will be assigned in the near future – of course, Dermot will remain a key SC member in support of this important effort.

Again, thanks – and please express my appreciation to the entire SC for their efforts and collaboration over the past year...

Warm Regards, Peter

Peter P. Stein, MD
Vice-president, Late Stage Development, Diabetes and Endocrinology
Merck Research Laboratories
Cell: (b) (6)
Office: 732-594-8509
Email: peter.stein@merck.com

Notice: This e-mail message, together with any attachments, contains information of Merck & Co., Inc. (2000 Galloping Hill Road, Kenilworth, New Jersey, USA 07033), and/or its affiliates Direct contact information for affiliates is available at http://www.merck.com/contact/contacts.html) that may be confidential, proprietary copyrighted and/or legally privileged. It is intended solely for the use of the individual or entity named on this message. If you are not the intended recipient, and have received this message in error, please notify us immediately by reply e-mail and then delete it from your system.

From: Wholley, David (FNIH) [T]
Sent: Mon, 14 Nov 2016 11:39:26 -0500
To: Collins, Francis (NIH/OD) [E]
Cc: Canet-Aviles, Rosa (FNIH) [T];Hoffmann, Steve (FNIH) [T];Whitaker, Sanya (FNIH) [T];Adam, Stacey (FNIH) [T];Spear, Nicole (FNIH) [T]
Subject: FW: Hever Group

Francis, response is below:

AMP:

- Alzheimer's Disease (two projects):
  - Project A: *Explore utility of tau imaging in two 5-year Phase II/III presymptomatic clinical trials*
    - 349 of total 1565 tau scans completed across two trials
  - Project B: *Conduct network analyses on 2000+ human brains to identify genetic nodes and networks linked to AD*
    - Data from 6 studies being shared publicly via Sage Knowledge Portal every 3 months; initial publications released
    - $1.6M in new grants awarded to analyze Project B data to identify biomarkers for target selection/engagement
- Type 2 Diabetes: *Create a knowledge portal with broad genotype/phenotype T2D and complications datasets and tools to enable target identification and understanding*
  - Portal now has 82,000 exome chip results, 17,000 exome sequences, and ~350,000 GWAS meta-analysis results from ethnically diverse populations
  - Federated UK hub developed by EBI to be released to the public 1/1/2017
- Rheumatoid Arthritis/Systemic Lupus Erythematosus: *Conduct single cell analysis of immune and tissue resident cell responsible for tissue damage in RA (synovium) and SLE (kidney)*
  - Novel SOPs for sample acquisition, processing, and tissue dissociation being submitted for publication
  - Extensive networks for acquisition of synovium (18 sites, 32 samples to date) and kidney (57 samples to date) established
  - Go/no-go milestone for project extended to January 2017 to allow final QC of CyTOF and single cell RNA seq data
- Parkinson's Disease (New, proposed initiative): [redacted] (b) (4) [redacted] *to 1) standardize assays and identify putative therapeutic targets for PD using 200 human brains and genetic datasets, and evaluate them in relevant human neuronal and animal model systems; and 2) combine and mine existing clinical study cohorts in order to develop biomarkers of response and target engagement*
  - [redacted] (b) (4)

Partnership for Accelerating Cancer Therapies (PACT) – *Proposed 5-year partnership with NIH and pharmaceutical industry partners focusing on 1) identification and validation of biomarkers for response and resistance to cancer therapies and 2) improving pre-clinical models for cancer therapies—with particular emphasis on immunotherapies and relevant combinations*

- [redacted] (b) (4)

- [redacted] (b) (4)

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, November 10, 2016 2:38 PM
To: Green, Eric (NIH/NHGRI) [E] [redacted] (b) (6) Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: FW: Hever Group...Update

Hi Eric and David,

See query below from Trevor Jones of the Hever Group.

Eric, can you provide any update on item 1? There was some discussion about inviting pharma reps to a discussion of how ClinGen was evolving. Did anything come of that?

David, can you get staff to provide bullets to answer the AMP and PACT questions?

I'll deal with the rest.

FC

From: Prof Trevor M Jones CBE [mailto:trevor.m.jones@btinternet.com]
Sent: Thursday, November 10, 2016 10:24 AM
To: Collins, Francis (NIH/OD) [E] [redacted] (b) (6); Collins, Francis (NIH/OD) [E] [redacted] (b) (6)
Subject: Hever Group...Update

Francis

You will remember that at our Hever meeting in April in NYC we discussed the "Diagnostics Initiative" and you updated the meeting on several key NIH projects

I am planning to send an update to those attending the Meeting and wonder whether you could let me have one or two "bullets " on each of the Action points listed below ?

My summary slides were as follows

---

1. **Diagnnostics Initiative**
   - Principal objective is to move from single Dx profiling to approved Multiplex assays as a prelude to full
     DNA sequencing, proteomic ,transcriptomics.
   - NIH ClinGen database curates literature and seeks to identify valid profiles
     ...Needs input from Hever initiative
   - Plus continuing the discussion on the regulatory complexities

e.g. peri/post-LOE drugs

ACTION NIH to examine possibility of hosting a meeting to review current projects / progress.

If so… poll interest of Hever members to participate .

FrC

---

2. NIH Update

- **AMP 3 projects**
  - Alzheimer's disease
  - Autoimmune disorders (rheumatoid arthritis and systemic lupus erythematosus)
  - Type 2 diabetes

  Possible New project proposals ……Parkinson's Disease

  ? Antibiotic Resistance Medicines and vaccines, schizophrenia ,others

FrC

- **National Cancer Moonshot**

  Industry (and Academia etc) being consulted re establishment of and priorities

  for Partnership for accelerating cancer therapies PACT

FrC

- **Precision Medicine Cohort (PMI Cohort)**

  Target is to enrol 1m (could be more !) by 2019

  Good links to UK Biobank

  34 longitudinal genomics data bases globally (with >100,000 subjects)

  …need to determine who might curate /combine the data

FrC

Best personal regards
Trevor

Prof Trevor M Jones CBE FMedSci

From: Wholley, David (FNIH) [T]
Sent: Sun, 7 Aug 2016 11:39:32 -0400
To: Collins, Francis (NIH/OD) [E]
Cc: Baker, Rebecca (NIH/OD) [E];Adam, Stacey (FNIH) [T];Rosema, Laura (NIH/OD) [E]
Subject: FW: PACT update and working group process

Hi Francis,

Not sure when you are back online, but when you get a chance thought maybe you could give Jay a gentle nudge to answer one way or the other. We are moving forward with orienting (b) (5) for the biomarker topic. Thanks David

---

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, July 28, 2016 11:11 PM
To: James.bradner@novartis.com
Cc: Hudson, Kathy (NIH/OD) [E] (b) (6); Lowy, Douglas (NIH/NCI) [E] (b) (6) Doroshow, James (NIH/NCI) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Adam, Stacey (FNIH) [T]<sadam@fnih.org>; Rosema, Laura (NIH/OD) [E] (b) (6) Baker, Rebecca (NIH/OD) [E] (b) (6)
Subject: PACT update and working group process

Dear Jay,

Thanks again for your words of support and enthusiasm for our partnership efforts at the New Democrats luncheon. I wanted to update you on some significant progress we've made on the Partnership for Accelerating Cancer Therapies (PACT), and to ask if Jeff Engelman could play a key leadership role in the effort.

The Vice-President cited PACT from the podium at the White House Cancer Moonshot Summit on June 29th as one of the more exciting opportunities in the Moonshot. After extensive conversations with potential partners and stakeholders, we've selected two focus areas for PACT:

1. **Identification and validation of biomarkers for the response to cancer therapies**
2. **Establishment of a platform for combination clinical trials**

We believe these areas will address the most pressing current needs in the immuno-oncology field, and are uniquely suited for a pre-competitive research collaboration.

Given the excitement and momentum generated by the Moonshot, we're eager to move PACT into the next phase of development, which involves convening a "Working Group" of experts from NCI, industry, patient groups, and academia to agree on a suitable research plan. From our experience with AMP, we

intend to select one industry scientist and one NCI representative to co-chair the Working Group. Both Doug Lowy and Jim Doroshow of NCI enthusiastically recommended Jeff to serve as the industry co-chair for focus area #2 in combination clinical trials.

The time commitment for Jeff would entail 3 teleconferences (a couple of hours each) and at least one in-person 2-day meeting in the early fall, with the key deliverable a white paper describing the consensus of the group on a common mission and a high level plan. Others from the Novartis Oncology group could also aid in the development of a detailed plan once the white paper is completed. Given how fast the field is moving, we'd like to solidify a plan and gather the necessary funding commitments by the end of this year, with a view to launching an effort in early 2017. We are engaging the Foundation for the NIH to manage this effort, and Jeff would be fully staffed by FNIH to make this successful.

Would you be willing to consider Jeff in this role? I will be out of the country next week, but David Wholley at FNIH (copied) can answer any detailed questions about the process, and I am happy to speak when I return on August 9th.

Best personal regards,

Francis

From: Wholley, David (FNIH) [T]
Sent: Tue, 26 Jul 2016 15:13:49 -0400
To: Collins, Francis (NIH/OD) [E]
Cc: Gadbois, Ellen (NIH/OD) [E];Spear, Nicole (FNIH) [T];Whitaker, Sanya (FNIH) [T]
Subject: FW: Revised AMP EC Slide
Attachments: Revised July EC Slides.pptx

Francis, here is the updated AMP T2D slide mentioning the T2DGenes publication you mentioned yesterday. Phil Smith is in the loop on this. Thanks, David

---

From: Spear, Nicole (FNIH) [T]
Sent: Tuesday, July 26, 2016 3:11 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Whitaker, Sanya (FNIH) [T] <swhitaker@fnih.org>
Subject: Revised AMP EC Slide

Hi David,

As requested, the attached slide has been updated to include the publication that Dr. Collins mentioned yesterday.

Phil responded that he has read the paper and is prepared to speak on it on Friday.

Thank you,

Nicole

T2D Knowledge Portal and Broader Research Community

GitHub

T2D Knowledge Portal codebase entitled: Framework for investigating Genetic Associations (FGA) is now available on GitHubThis release is in keeping with the AMP T2D Consortium goals to share all code, thereby enabling distributed software development and expanded opportunities for collaboration and growth.


ARTICLE

doi:10.1038/nature18642

The genetic architecture of type 2 diabetes

A list of authors and affiliations appears in the online version of the paper

Nature July, 2016Recent T2D GENES publication using data available through the type 2 diabetes genetics portal developed as part of the Accelerating Medicines Partnership


REVIEWS

Type 2 diabetes: genetic data sharing to advance complex disease research

Jason Flannick and Jose C. Florez

Nature Reviews Genetics July, 2016Flannick and Florez's overview of type 2 diabetes genetics, with focus on how data sharing via a knowledge base portal could advance research and clinical translation in the field

NIH - 001313

From: Wholley, David (FNIH) [T]
Sent: Thu, 28 Jul 2016 13:38:56 -0400
To: Collins, Francis (NIH/OD) [E]
Cc: Gadbois, Ellen (NIH/OD) [E]
Subject: FW: Semillon Pharmaceuticals, Inc. AMP-AD proposal
Attachments: Semillon Pharmaceuticals Inc AMP-AD Application - July 2016.pdf, FINAL_AMP-MCI2AD.pdf

Francis, just a heads up. In the interest of generating a timely response, I have added this to the agenda for the EC call tomorrow. Hope that is OK.
David

From: Hodes, Richard (NIH/NIA) [E]
Sent: Wednesday, July 27, 2016 6:11 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnih.org>; Ryan, Laurie (NIH/NIA) [E] (b) (6); Masliah, Eliezer (NIH/NIA/ERP) [E] (b) (6); Petanceska, Suzana (NIH/NIA) [E] (b) (6)
Subject: Re: Semillon Pharmaceuticals, Inc. AMP-AD proposal

Sounds right.
Thanks

From: Wholley, David (FNIH) [T]
Sent: Wednesday, July 27, 2016 5:56 PM
To: Hodes, Richard (NIH/NIA) [E]
Cc: Canet-Aviles, Rosa (FNIH) [T]; Ryan, Laurie (NIH/NIA) [E]; Masliah, Eliezer (NIH/NIA/ERP) [E]; Petanceska, Suzana (NIH/NIA) [E]
Subject: RE: Semillon Pharmaceuticals, Inc. AMP-AD proposal

I would include it in the EC materials (to go out tomorrow) and leave a spot on the agenda to have you and the other EC members comment upon it, what action should be taken. FNIH would follow up with Allen.

My take is that this is rather outside the aims of AMP, since it is much later stage than target validation, would like be difficult to cast as fully pre-competitive, and would likely have difficulty attracting the requisite matching private sector funds (and perhaps NIH funds) that are a hallmark of the AMP partnership construct. But that is just me, the EC needs to decide…

Hope that helps.
David

From: Hodes, Richard (NIH/NIA) [E]
Sent: Wednesday, July 27, 2016 5:49 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnih.org>; Ryan, Laurie (NIH/NIA) [E]

(b) (6)>; Masliah, Eliezer (NIH/NIA/ERP) [E] (b) (6); Petanceska, Suzana (NIH/NIA) [E] (b) (6)
Subject: Fw: Semillon Pharmaceuticals, Inc. AMP-AD proposal
Importance: High

Hi David

(b) (5)

Thanks
Richard

From: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Sent: Wednesday, July 27, 2016 5:31 PM
To: Hodes, Richard (NIH/NIA) [E]
Cc: Canet-Aviles, Rosa (FNIH) [T]; Ryan, Laurie (NIH/NIA) [E]; Petanceska, Suzana (NIH/NIA) [E]
Subject: FW: Semillon Pharmaceuticals, Inc. AMP-AD proposal

Dear Richard:
Please see the application for a new initiative in AMP in Alzheimer's disease submitted yesterday by Allen Roses, originally addressed to Laurie Ryan. We have consulted with Laurie about this and agreed we should let Allen know that FNIH is handling these requests (which has been done). While I am not sure anyone has (b) (4) laying around to do this (!) we probably do need to let the AMP EC know about it, since Dr. Roses has gone to the trouble of formally submitting an AMP concept form. We could raise this as early as this Friday morning's EC teleconference, but wanted to give you a heads up and get your guidance on the matter first.

Please let me know how you'd like to handle.

Regards,
David Wholley

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

From: Wholley, David (FNIH) [T]
Sent: Mon, 11 Jul 2016 17:40:48 -0400
To: Collins, Francis (NIH/OD) [E]
Cc: Melencio, Cheryl (FNIH) [T];Morgan, Emily (FNIH) [T]
Subject: FW: AMP Executive Committee Teleconference - July 29, 2016

Hi Francis,
Please see below. OK to let Martin substitute? We are still counting up likely attendees for the next AMP EC which is scheduled for Friday July 29.

From: Melencio, Cheryl (FNIH) [T]
Sent: Monday, July 11, 2016 9:20 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: FW: AMP Executive Committee Teleconference - July 29, 2016

Dr. Dolsten is not available July 29 and Ann wants to know if Morten Sogaard can attend in his place.

Thank you

Cheryl

From: Protasiewicz, Ann [mailto:Ann.Protasiewicz@pfizer.com]
Sent: Thursday, June 30, 2016 8:26 PM
To: Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>
Subject: RE: AMP Executive Committee Teleconference - July 29, 2016

Hi Cheryl,

Any word on whether or not Morten will be permitted to participate?

Ann

Ann Martin Protasiewicz
Executive Assistant to
Mikael Dolsten, President
Worldwide Research and Development
Pfizer Inc.
235 East 42nd Street, Floor 22
New York, NY 10017
212-733-5859 (Office)
(b) (6) (Mobile)
E-Mail – ann.protasiewicz@pfizer.com

From: Melencio, Cheryl (FNIH) [T] [mailto:cmelencio@fnih.org]
Sent: Thursday, June 16, 2016 2:03 PM
To: Protasiewicz, Ann
Subject: RE: AMP Executive Committee Teleconference - July 29, 2016

I forwarded your note to David Wholley. I am waiting his reply. I'll let you know as soon as he replies?

Cheryl

From: Protasiewicz, Ann [mailto:Ann.Protasiewicz@pfizer.com]
Sent: Thursday, June 16, 2016 2:01 PM
To: Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>
Subject: RE: AMP Executive Committee Teleconference - July 29, 2016

Cheryl,

I am following up on my inquiry below. Once you have a chance to look into this, let me know if this will be permissible.

Ann

Ann Martin Protasiewicz
Executive Assistant to
Mikael Dolsten, President
Worldwide Research and Development
Pfizer Inc.
235 East 42nd Street, Floor 22
New York, NY 10017
212-733-5859 (Office)
(b) (6) (Mobile)
E-Mail – ann.protasiewicz@pfizer.com

From: Protasiewicz, Ann
Sent: Monday, June 13, 2016 6:35 PM
To: 'Melencio, Cheryl (FNIH) [T]'
Subject: AMP Executive Committee Teleconference - July 29, 2016

Cheryl,

Mikael Dolsten now has a conflict with an all-day meeting on Friday, July 29. Therefore, he asked me to reach out to you to ask if it would be permissible for Morten Sogaard to participate in the AMP meeting in his stead.

Kindly let me know if that will be okay.

Regards,

Ann

Ann Martin Protasiewicz
Executive Assistant to
Mikael Dolsten, President
Worldwide Research and Development
Pfizer Inc.
235 East 42nd Street, Floor 22
New York, NY 10017
212-733-5859 (Office)
(b) (6) (Mobile)
E-Mail – ann.protasiewicz@pfizer.com

-----Original Appointment-----
From: Melencio, Cheryl (FNIH) [T] [mailto:cmelencio@fnih.org]
Sent: Monday, March 7, 2016 4:17 PM
To: 'Melencio, Cheryl (FNIH) [T]'; Buckholtz, Neil (NIH/NIA) [C]; Canet-Aviles, Rosa (FNIH) [T]; Carter, Robert (NIH/NIAMS) [E]; Collins, Francis (NIH/OD) [E]; Cuss, Francis; Decker, Mike; Dolsten, Mikael; FNIH Central Account; Gadbois, Ellen (NIH/OD) [E]; Hodes, Richard (NIH/NIA) [E]; Hodge, Martin; Hoffmann, Steve (FNIH) [T]; Hudson, Kathy (NIH/OD) [E]; Katz, Stephen I. (NIH/NIAMS) [E]; Lea, Allison (NIH/OD) [C]; Li, Rose; Lifton, Richard; Lundberg, Jan; Paltoo, Dina (NIH/OD) [E]; Rodgers, Griffin (NIH/NIDDK) [E]; Ryan, Laurie (NIH/NIA) [E]; Serrate-Sztein, Susana (NIH/NIAMS) [E]; Smith, Philip (NIH/NIDDK) [E]; Sorrow, Kathleen; Spear, Nicole (FNIH) [T]; Stein, Peter; Terry, Sharon MA; Whitaker, Sanya (FNIH) [T]; Wholley, David (FNIH) [T]; Boskent, Celeste (NIH/OD) [E]; Bronson, Charlette (NIH/NIA) [E]; Cappello, Elizabeth; Clark, Katie; Craver, Stephanie (NIH/NIAMS) [E]; Doswell, Greta (NIH/OD) [E]; Edmonds, Pamela; Fraser, Christe (NIH/NIAMS) [C]; Gwaldis, Janice; Ilchyk, Yuliya; McManus, Ayanna (NIH/OD) [E]; Meltzer, Sherry (NIH/NIAMS) [E]; Murza, Tanya; Poole, Charlene (NIH/NIDDK) [E]; Protasiewicz, Ann; Schulke, Hilda (NIH/OD) [E]; Sheehan, Joan (NIH/NIA) [E]; Wilkerson, Anita D. (NIH/NIDDK) [E]; Wood, Gretchen (NIH/OD) [E]; Zander, Debra
Subject: AMP Executive Committee Teleconference
When: Friday, July 29, 2016 8:00 AM-9:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: (b) (6) France: (b) (6) Participant Code: (b) (6) Moderator Code: (b) (6) (b)# Project Code: (b) (6)

From: Wholley, David (FNIH) [T]
Sent: Wed, 21 Sep 2016 10:01:16 -0400
To: Collins, Francis (NIH/OD) [E]
Subject: FW: AMP Executive Committee Teleconference

FYI, this seems to be about the time we get this message...he was in confirmed status two weeks ago.

From: Melencio, Cheryl (FNIH) [T]
Sent: Wednesday, September 21, 2016 9:59 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: FW: AMP Executive Committee Teleconference

This just came in from Jan Lundberg's office.

-----Original Appointment-----
From: Pamela J Edmonds [mailto:edmonds_pamela_j@lilly.com] **On Behalf Of** Jan Lundberg
Sent: Wednesday, September 21, 2016 9:58 AM
To: Melencio, Cheryl (FNIH) [T]
Subject: Declined: AMP Executive Committee Teleconference
When: Friday, September 23, 2016 8:00 AM-9:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: (b) (6) France: 0805 770 131 Participant Code: (b) (6) Moderator Code: (b) (6) Project Code: (b) (6)

Cheryl, Jan has a priority conflict and will now not be available to participate on the call. Thanks, Pam

From: Wholley, David (FNIH) [T]
Sent: Thu, 15 Dec 2016 09:45:11 -0500
To: Collins, Francis (NIH/OD) [E]
Cc: Katz, Stephen I. (NIH/NIAMS) [E];Carter, Robert (NIH/NIAMS) [E];Hodge, Martin;Hoffmann, Steve (FNIH) [T];Melencio, Cheryl (FNIH) [T]
Subject: Fw: AMP Extended Executive Committee Materials Attached

Please note below. We will make sure Dr. Nestle receives the document.
Sent from my BlackBerry 10 smartphone.

From: Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>
Sent: Thursday, December 15, 2016 8:13 AM
To: Wholley, David (FNIH) [T]
Subject: FW: AMP Extended Executive Committee Materials Attached

fyi

From: Catherine.Jacquet@sanofi.com [mailto:Catherine.Jacquet@sanofi.com]
Sent: Thursday, December 15, 2016 7:52 AM
To: Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>
Cc: PhilipJust.Larsen@sanofi.com; Frank.Nestle@sanofi.com
Subject: RE: AMP Extended Executive Committee Materials Attached

Dear Cheryl,

Please kindly note that due to a last minute conflict, Dr. Zerhouni will not be available to attend this conference tomorrow. Dr. Philip Larsen and Dr. Frank Nestle –both here copied- from Sanofi will represent him for this session.

In preparation for the meeting, could you send Dr. Nestle the complete RA/Lupus proposal document? This would be much appreciated.

Many thanks in advance.
Best regards,
Catherine

De : Melencio, Cheryl (FNIH) [T] [mailto:cmelencio@fnih.org]
Envoyé : mercredi 14 décembre 2016 23:07
À : Buckholtz, Neil (NIH/NIA) [C]; Canet-Aviles, Rosa (FNIH) [T]; Carter, Robert (NIH/NIAMS) [E]; Collins, Francis (NIH/OD) [E]; Cuss, Francis; Decker, Mike; Dolsten, Mikael; Gadbois, Ellen (NIH/OD) [E]; Hodes, Richard (NIH/NIA) [E]; Hodge, Martin; Hoffmann, Steve (FNIH) [T]; Hudson, Kathy (NIH/OD) [E]; Katz, Stephen I. (NIH/NIAMS) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Lea, Allison (NIH/OD) [E]; Lifton, Richard; Lundberg, Jan; Menetski, Joseph (FNIH) [T]; Paltoo, Dina (NIH/OD) [E]; Rodgers, Griffin (NIH/NIDDK) [E]; Ryan, Laurie (NIH/NIA) [E]; Serrate-Sztein, Susana (NIH/NIAMS) [E]; Smith, Philip (NIH/NIDDK) [E]; Spear, Nicole (FNIH) [T]; Sutherland, Margaret (NIH/NINDS) [E]; Tabak, Lawrence (NIH/OD) [E]; Terry, Sharon MA; Thomas, Melissa; Wholley, David (FNIH) [T]; Artavantis-Tsakonas, Spyros; Lon Cardon; Chin, Bill; Hait, Bill; Miletich, Joseph; Oyler, Cat; Plump, Andrew; Sullivan, Jim; Woodcock, Janet (FDA/CDER); Zerhouni, Elias PH/FR; Alesci, Salvatore; Carrillo, Maria; Collins, Mary;

Eakin, Guy; Fillit, Howard; Goldmuntz, Ellen (NIH/NIAID) [E]; Sheri Grabus; Hanrahan, Leslie; Hedrick, Joe; Hendrix, James; Lappin, Debra; List, James; Marchiolo, Eryn; Jennifer McCulley; Nickerson, Helen; Niskar, Amanda; Pragnell, Marlon; Rigby, William F. C.; Rotrosen, Daniel (NIH/NIAID) [E]; Tarrant, Teresa; Vallance, Patrick
Cc : Boskent, Celeste (NIH/OD) [E]; Bronson, Charlette (NIH/NIA) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Clark, Katie; Craver, Stephanie (NIH/NIAMS) [E]; Doswell, Greta (NIH/OD) [E]; Edmonds, Pamela; Yuliya Ilchyk; McManus, Ayanna (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]; Meltzer, Sherry (NIH/NIAMS) [E]; Morgan, Emily (FNIH) [T]; Tanya Murza; NIHDirectorMeetings; Poniente, Josefina; Poole, Charlene (NIH/NIDDK) [C]; Protasiewicz, Ann; Schulke, Hilda (NIH/OD) [E]; Sheehan, Joan (NIH/NIA) [E]; Simon, Dina (NIH/OD) [C]; Walker, Paula (NIH/NINDS) [E]; Wood, Gretchen (NIH/OD) [E]; Zander, Debra; Burkhardt, Carolyn; Choisnet, Tracey; Corsini, Linda; Hays, Marian; Jacquet, Catherine PH/FR; Jones, Kim; Koch, Kellie; LaViolette, Rita; Ligon, Sharnell (CDER) (FDA/CDER); Perala, Mie; Profrock, Kathy; Schuster, Donna; Sultani, Tila
Objet : AMP Extended Executive Committee Materials Attached

Good afternoon,

Attached are the materials for Friday's call of the AMP Extended Executive Committee. This call will begin at 8 a.m. Eastern time. An Adobe Connect link has been set up: (b) (6).

As a reminder, the call in credentials are: US/Canada: (b) (6) France: 0805 770 131 Germany: 0800 588 9700 UK: 08080 238 9879 Switzerland: 0800 661 155 Participant Code: (b) (6) (b) (6)

We look forward to the call.

Cheryl

Cheryl Melencio
Executive Assistant, Research Partnerships
Foundation for the National Institutes of Health
9650 Rockville Pike | Bethesda, MD 20814 | www.fnih.org
Direct (301) 402-4970 | Fax (301) 480-2752

Combined Federal Campaign (CFC) #29165
For 13 consecutive years, Charity Navigator has rated the FNIH as an organization that *exceeds industry standards.*

FNIH
Foundation for the National Institutes of Health

To facilitate conservation of earth's precious natural resources please consider the environment before printing this email.
Confidentiality Notice: *Information contained in this e-mail and attachments may be legally privileged and confidential. If you are not an intended recipient, you are hereby notified that dissemination, distribution or copying this e-mail and attachments is strictly prohibited; please delete the e-mail and attachments immediately.*

From: Wholley, David (FNIH) [T]
Sent: Thu, 10 Nov 2016 12:10:03 -0500
To: Collins, Francis (NIH/OD) [E];Gadbois, Ellen (NIH/OD) [E]
Cc: Gadbois, Ellen (NIH/OD) [E];Lea, Allison (NIH/OD) [E];NIHDirectorMeetings;Hudson, Kathy (NIH/OD) [E];Doswell, Greta (NIH/OD) [E];Boskent, Celeste (NIH/OD) [E];Di Mantova, Emma (NIH/OD) [E];McManus, Ayanna (NIH/OD) [E];Wood, Gretchen (NIH/OD) [E];Hoffmann, Steve (FNIH) [T];Canet-Aviles, Rosa (FNIH) [T];Spear, Nicole (FNIH) [T];Whitaker, Sanya (FNIH) [T];Melencio, Cheryl (FNIH) [T];Morgan, Emily (FNIH) [T];Menetski, Joseph (FNIH) [T]
Subject: Materials for AMP EC pre-call at 1:30 PM
Attachments: AMP EC Slides November 18 2016 DRAFT.pptx, Copy of AMP - EC Attendance for Nov18.xlsx, Copy of AMP Extended EC Attendance -- December 16 2016.xlsx
Importance: High

Francis:
Here are 1) the suggested slides for our AMP EC pre-call 2) the current planned attendance for the November 18 EC call 3) preliminary responses for the December 16 Extended EC call. Look forward to our discussion.

Thanks, David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
9650 Rockville Pike | Bethesda, MD 20814 | **fnih.org**
Direct (301) 594-6343 | dwholley@fnih.org



For 13 consecutive years, Charity Navigator has rated the FNIH as an organization that *exceeds industry standards.*

Accelerating Medicines PartnershipCore Executive Committee Update

18 November, 2016



FNIH
Foundation for the National Institutes of Health

Contents

(b) (5)

Accelerating Medicines PartnershipAMP Parkinson's Disease(Program Development Update)

FNIH

Foundation for the National Institutes of Health

NIH - 001337



(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

Accelerating Medicines PartnershipAlzheimer's Disease

FNIH

Foundation for the National Institutes of Health

NIH - 001343



(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

AMP AD F2F Annual Meeting 2016

- (b) (5)



NIH - 001347

Accelerating Medicines PartnershipType 2 Diabetes

FNIH

Foundation for the
National Institutes of Health

NIH - 001348



(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

Accelerating Medicines PartnershipRA/SLE

FNIH

Foundation for the
National Institutes of Health

NIH - 001359



(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

Attendance for AMP EC -- 11/18/16

Name	Attendance	Response
Melencio, Cheryl (FNIH) [T]	Meeting Organizer	None
Buckholtz, Neil (NIH/NIA) [C]	Required Attendee	Accepted
Canet-Aviles, Rosa (FNIH) [T]	Required Attendee	Accepted
Carter, Robert (NIH/NIAMS) [E]	Required Attendee	Accepted
Collins, Francis (NIH/OD) [E]	Required Attendee	Accepted
Cuss, Francis	Required Attendee	Accepted
Decker, Mike	Required Attendee	Accepted
Dolsten, Mikael	Required Attendee	Accepted (prefers 7:30 a.m.)
Gadbois, Ellen (NIH/OD) [E]	Required Attendee	Accepted
Hodes, Richard (NIH/NIA) [E]	Required Attendee	Declined
Hodge, Martin	Required Attendee	Accepted
Hoffmann, Steve (FNIH) [T]	Required Attendee	Accepted
Hudson, Kathy (NIH/OD) [E]	Required Attendee	
Katz, Stephen I. (NIH/NIAMS) [E]	Required Attendee	Accepted
Koroshetz, Walter (NIH/NINDS) [E]	Required Attendee	Accepted
Lea, Allison (NIH/OD) [C]	Required Attendee	Accepted
Lifton, Richard	Required Attendee	Accepted
Lundberg, Jan	Required Attendee	Accepted - will call in from Sweden
Paltoo, Dina (NIH/OD) [E]	Required Attendee	Accepted
Rodgers, Griffin (NIH/NIDDK) [E]	Required Attendee	Accepted
Ryan, Laurie (NIH/NIA) [E]	Required Attendee	
Serrate-Sztein, Susana (NIH/NIAMS) [E]	Required Attendee	
Smith, Philip (NIH/NIDDK) [E]	Required Attendee	Accepted
Spear, Nicole (FNIH) [T]	Required Attendee	Accepted
Sutherland, Margaret (NIH/NINDS) [E]	Required Attendee	
Terry, Sharon MA	Required Attendee	Declined in CA so it is 4 a.m.
Whitaker, Sanya (FNIH) [T]	Required Attendee	Declined - on leave
Wholley, David (FNIH) [T]	Required Attendee	Accepted

AMP Extended EC 12/16/16

Name	Attendance	Response
Melencio, Cheryl (FNIH) [T]	Meeting Organizer	None
Artavantis-Tsakonas, Spyros	Required Attendee	Tentative
Cardon, Lon	Required Attendee	Accepted
Chin, Bill	Required Attendee	None
Hait, Bill	Required Attendee	Accepted
Miletich, Joseph	Required Attendee	None
Oyler, Cat	Required Attendee	Accepted
Plump, Andrew	Required Attendee	Accepted
Sullivan, Jim	Required Attendee	Accepted
Woodcock, Janet (FDA/CDER)	Required Attendee	Accepted
Zerhouni, Elias	Required Attendee	None
Buckholtz, Neil (NIH/NIA) [C]	Required Attendee	Accepted
Canet-Aviles, Rosa (FNIH) [T]	Required Attendee	Accepted
Carter, Robert (NIH/NIAMS) [E]	Required Attendee	None
Collins, Francis (NIH/OD) [E]	Required Attendee	None
Cuss, Francis	Required Attendee	Tentative
Decker, Mike	Required Attendee	Accepted
Dolsten, Mikael	Required Attendee	Accepted
Gadbois, Ellen (NIH/OD) [E]	Required Attendee	Accepted
Hodes, Richard (NIH/NIA) [E]	Required Attendee	Accepted
Hodge, Martin	Required Attendee	Accepted
Hoffmann, Steve (FNIH) [T]	Required Attendee	Accepted
Hudson, Kathy (NIH/OD) [E]	Required Attendee	None
Katz, Stephen I. (NIH/NIAMS) [E]	Required Attendee	None
Lea, Allison (NIH/OD) [C]	Required Attendee	None
Lifton, Richard	Required Attendee	None
Lundberg, Jan	Required Attendee	Accepted
Paltoo, Dina (NIH/OD) [E]	Required Attendee	Accepted
Rodgers, Griffin (NIH/NIDDK) [E]	Required Attendee	Accepted
Ryan, Laurie (NIH/NIA) [E]	Required Attendee	None
Serrate-Sztein, Susana (NIH/NIAMS) [E]	Required Attendee	None
Smith, Philip (NIH/NIDDK) [E]	Required Attendee	None
Spear, Nicole (FNIH) [T]	Required Attendee	Accepted
Terry, Sharon	Required Attendee	Accepted
Whitaker, Sanya (FNIH) [T]	Required Attendee	None
Wholley, David (FNIH) [T]	Required Attendee	Accepted
Alesci, Salvatore	Required Attendee	Tentative
Carrillo, Maria	Required Attendee	Tentative
Fillit, Howard	Required Attendee	Accepted
Hanrahan, Leslie	Required Attendee	Accepted
Hedrick, Joe	Required Attendee	Tentative
Hendrix, James	Required Attendee	None
List, James	Required Attendee	Tentative
Marchiolo, Eryn	Required Attendee	None
Nickerson, Helen	Required Attendee	None

Pragnell, Marlon	Required Attendee	Accepted
Rigby, William F. C.	Required Attendee	None
Vallance, Patrick	Required Attendee	Declined
Koroshetz, Walter (NIH/NINDS) [E]	Required Attendee	None
Sutherland, Margaret (NIH/NINDS) [E]	Required Attendee	Accepted

From: Wholley, David (FNIH) [T]
Sent: Thu, 15 Sep 2016 21:37:09 -0400
To: Collins, Francis (NIH/OD) [E]
Cc: Gadbois, Ellen (NIH/OD) [E];Lea, Allison (NIH/OD) [C];Boskent, Celeste (NIH/OD) [E];Wood, Gretchen (NIH/OD) [E];Di Mantova, Emma (NIH/OD) [E];Hoffmann, Steve (FNIH) [T];Whitaker, Sanya (FNIH) [T];Spear, Nicole (FNIH) [T];Canet-Aviles, Rosa (FNIH) [T];Melencio, Cheryl (FNIH) [T];Morgan, Emily (FNIH) [T]
Subject: Materials for tomorrow morning's AMP pre-call
Attachments: AMP EC Slides September 23, 2016 Draft.pptx, Copy of September 23 AMP EC Telecon.xlsx, 2016-07-29_AMP_EC_Telecon_minutes.docx
Importance: High

Francis, sorry for the late arrival of these but as you can see there are some late-breaking slides we are waiting on for PD and RA/SLE that I waited on. Please find attached the proposed slide deck for our Sept 23 EC call (with some placeholder slides), the current count of attendees for the meeting (good so far), and the minutes from our last call in July. Look forward to speaking with you in the morning.

David

Accelerating Medicines PartnershipCore Executive Committee Meeting

23 September, 2016



FNIH
Foundation for the National Institutes of Health

(b) (4), (b) (5)

(b) (4), (b) (5)

Accelerating Medicines PartnershipAMP Parkinson's Disease(Program Development Update)

FNIH

Foundation for the National Institutes of Health

NIH - 001375



(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

Accelerating Medicines PartnershipRA/SLE

FNIH

Foundation for the
National Institutes of Health

NIH - 001381



(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (5)

Accelerating Medicines PartnershipAlzheimer's Disease

FNIH

Foundation for the National Institutes of Health

NIH - 001392



(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

AMP AD F2F Annual Meeting 2016

(b) (5)



NIH - 001396

Accelerating Medicines PartnershipType 2 Diabetes

FNIH

Foundation for the
National Institutes of Health

NIH - 001397



(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

Executive Committee

- **Next MeetingsAMP EC: Friday, October 28 from 8:00am – 9:00am Eastern US Time**

Attendance -- September 23, 2016 AMP EC

Name	Attendance	Response
Melencio, Cheryl (FNIH) [T]	Meeting Organizer	None
Buckholtz, Neil (NIH/NIA) [C]	Required Attendee	Accepted
Canet-Aviles, Rosa (FNIH) [T]	Required Attendee	Accepted
Carter, Robert (NIH/NIAMS) [E]	Required Attendee	Accepted
Collins, Francis (NIH/OD) [E]	Required Attendee	Accepted
Cuss, Francis	Required Attendee	Accepted
Decker, Mike	Required Attendee	Accepted
Dolsten, Mikael	Required Attendee	Accepted
Gadbois, Ellen (NIH/OD) [E]	Required Attendee	Accepted
Hodes, Richard (NIH/NIA) [E]	Required Attendee	Accepted
Hodge, Martin	Required Attendee	Accepted
Hoffmann, Steve (FNIH) [T]	Required Attendee	Accepted
Hudson, Kathy (NIH/OD) [E]	Required Attendee	None
Katz, Stephen I. (NIH/NIAMS) [E]	Required Attendee	Accepted
Koroshetz, Walter	Required Attendee	None
Lea, Allison (NIH/OD) [C]	Required Attendee	Accepted
Lifton, Richard	Required Attendee	None
Lundberg, Jan	Required Attendee	Accepted
Paltoo, Dina (NIH/OD) [E]	Required Attendee	Accepted
Rodgers, Griffin (NIH/NIDDK) [E]	Required Attendee	Accepted
Ryan, Laurie (NIH/NIA) [E]	Required Attendee	Accepted
Scherzer, Clemens	Required Attendee	Accepted
Serrate-Sztein, Susana (NIH/NIAMS) [E]	Required Attendee	None
Smith, Philip (NIH/NIDDK) [E]	Required Attendee	Accepted
Spear, Nicole (FNIH) [T]	Required Attendee	Accepted
Stein, Peter	Required Attendee	Accepted
Stone, David	Required Attendee	Accepted
Sutherland, Margaret	Required Attendee	None
Terry, Sharon	Required Attendee	Accepted
Whitaker, Sanya (FNIH) [T]	Required Attendee	Accepted
Wholley, David (FNIH) [T]	Required Attendee	Accepted

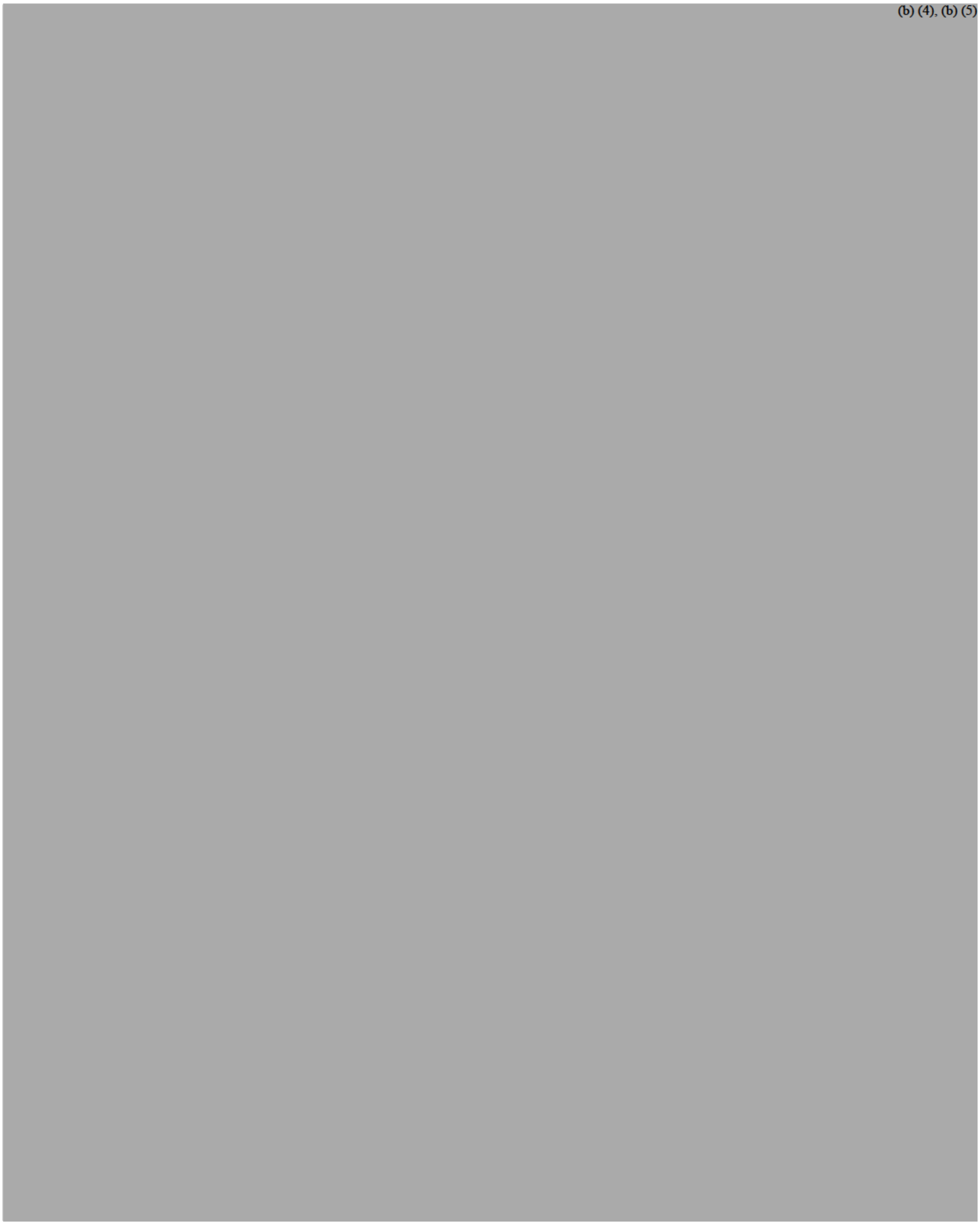
Foundation for the National Institutes of Health
Accelerating Medicines Partnership
Core Executive Committee
Teleconference Meeting Minutes
Friday, July 29, 2016
8:00 a.m. – 9:00 a.m. ET

Participants:

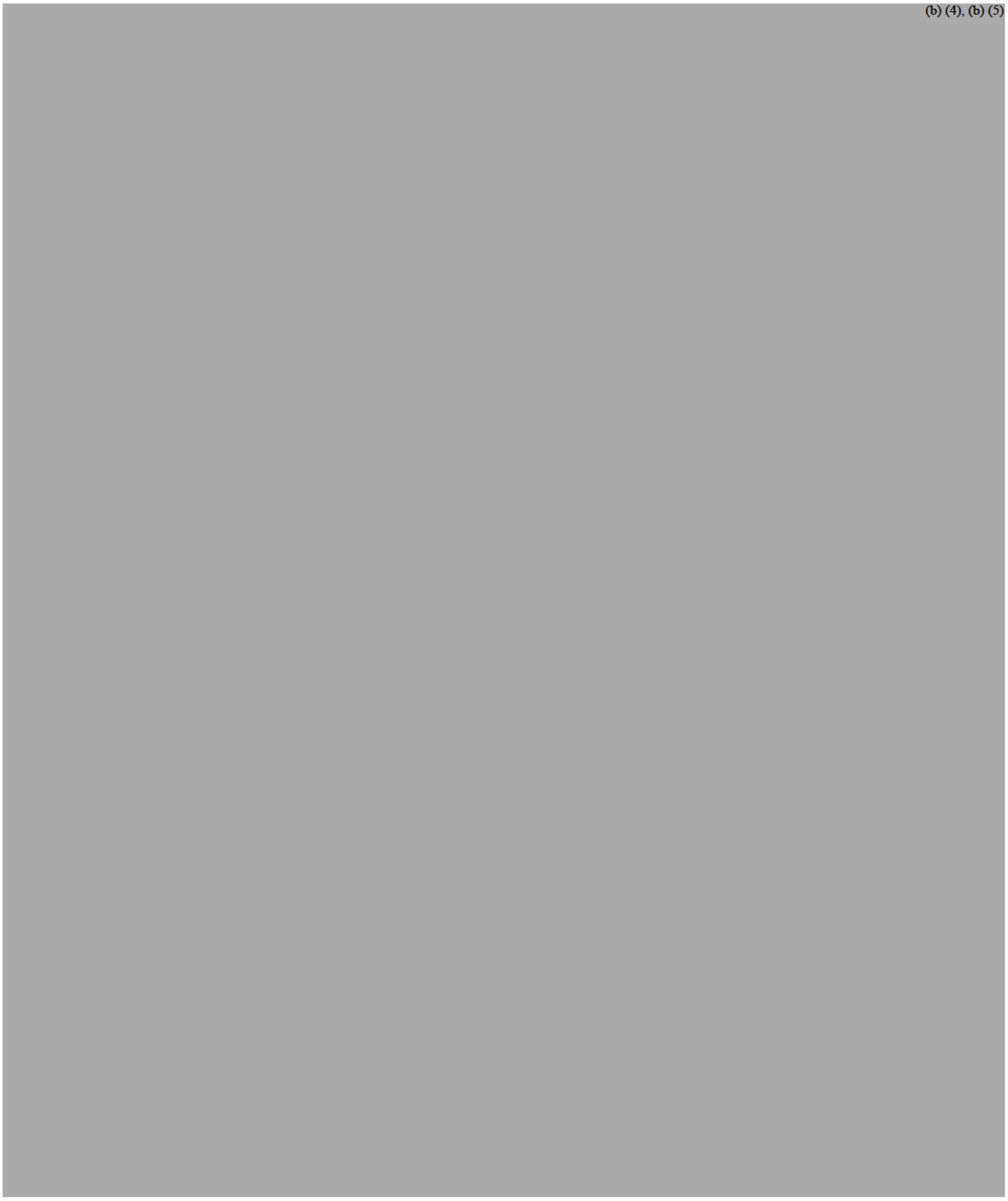
Neil Buckholtz (NIH/NIA), Rosa Canet- Aviles (FNIH), Robert Carter (NIH/NIAMS), Francis Collins (NIH/OD), Francis Cuss (BMS), Michael Decker (AbbVie), Ellen Gadbois (NIH/OD), Richard Hodes (NIH/NIA), Marty Hodge (Pfizer), Steve Hoffmann (FNIH), Walter Koroshetz (NIH/NINDS), Allison Lea (NIH/OD), Jan Lundberg (Lilly), Dina Paltoo (NIH/OD), Susana Serrate-Sztein (NIH/NIAMS), Philip Smith (NIH/NIDDK), Nicole Spear (FNIH), Peter Stein (Merck), Sanya Fanous Whitaker (FNIH), David Wholley (FNIH)

(b) (4), (b) (5)

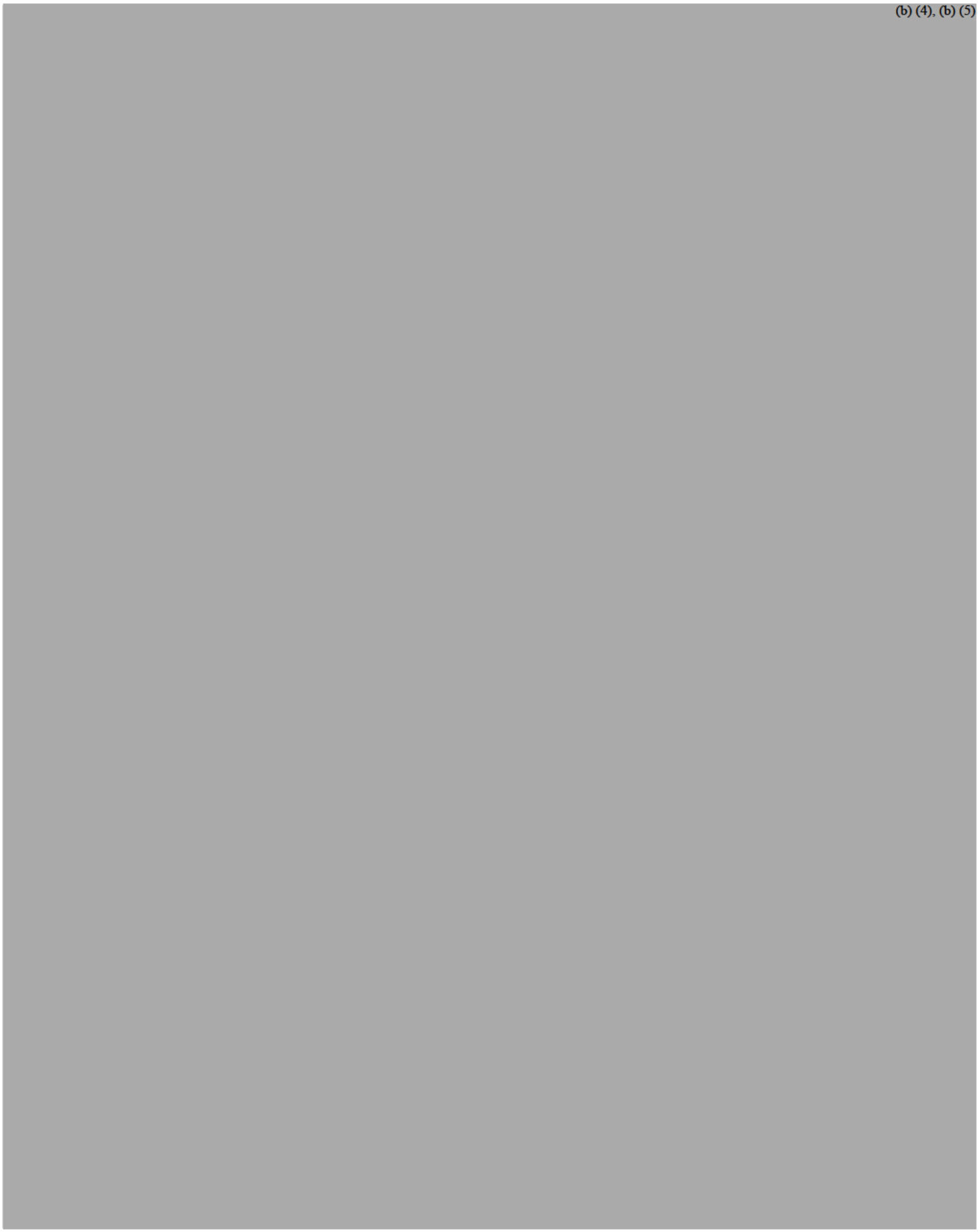


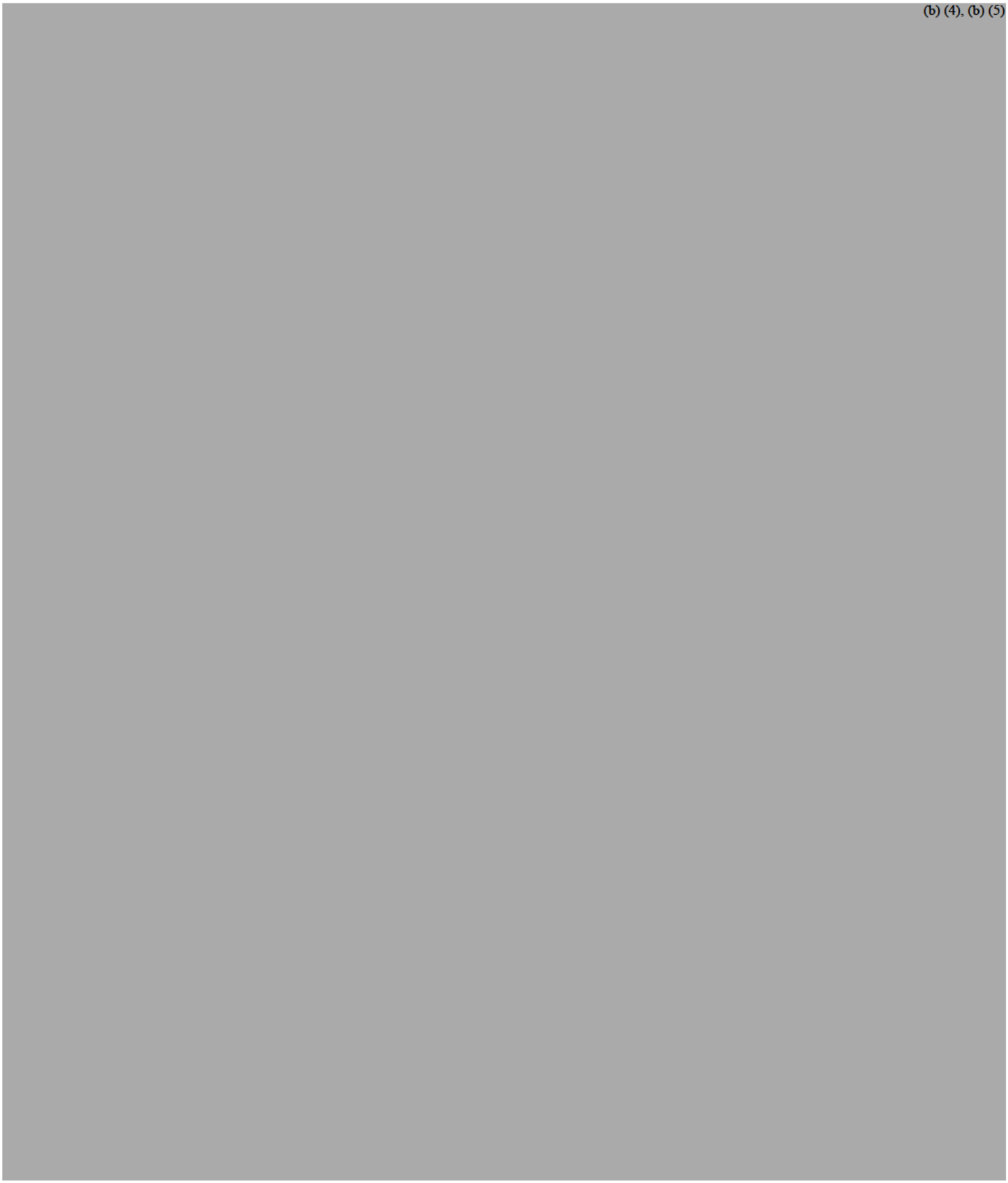


(b) (4), (b) (5)



(b) (4), (b) (5)




(b) (4), (b) (5)

From: Melencio, Cheryl (FNIH) [T] on behalf of Wholley, David (FNIH) [T]
Sent: Wed, 14 Dec 2016 13:41:31 -0500
To: Buckholtz, Neil (NIH/NIA) [C];Canet-Aviles, Rosa (FNIH) [T];Carter, Robert (NIH/NIAMS) [E];Collins, Francis (NIH/OD) [E];Cuss, Francis;Decker, Mike;Dolsten, Mikael;Gadbois, Ellen (NIH/OD) [E];Hodes, Richard (NIH/NIA) [E];Hodge, Martin;Hoffmann, Steve (FNIH) [T];Hudson, Kathy (NIH/OD) [E];Katz, Stephen I. (NIH/NIAMS) [E];Koroshetz, Walter (NIH/NINDS) [E];Lea, Allison (NIH/OD) [E];Lifton, Richard;Lundberg, Jan;Menetski, Joseph (FNIH) [T];Paltoo, Dina (NIH/OD) [E];Rodgers, Griffin (NIH/NIDDK) [E];Ryan, Laurie (NIH/NIA) [E];Serrate-Sztein, Susana (NIH/NIAMS) [E];Smith, Philip (NIH/NIDDK) [E];Spear, Nicole (FNIH) [T];Sutherland, Margaret (NIH/NINDS) [E];Tabak, Lawrence (NIH/OD) [E];Terry, Sharon MA;Thomas, Melissa;Wholley, David (FNIH) [T];Artavantis-Tsakonas, Spyros;Lon Cardon;Chin, Bill;Hait, Bill;Miletich, Joseph;Oyler, Cat;Plump, Andrew;Sullivan, Jim;Woodcock, Janet (FDA/CDER);Zerhouni, Elias;Alesci, Salvatore;Carrillo, Maria;Collins, Mary;Eakin, Guy;Fillit, Howard;Goldmuntz, Ellen (NIH/NIAID) [E];Sheri Grabus;Hanrahan, Leslie;Hedrick, Joe;Hendrix, James;Lappin, Debra;List, James;Marchiolo, Eryn;Jennifer McCulley;Nickerson, Helen;Niskar, Amanda;Pragnell, Marlon;Rigby, William F. C.;Rotrosen, Daniel (NIH/NIAID) [E];Tarrant, Teresa;Vallance, Patrick
Cc: Boskent, Celeste (NIH/OD) [E];Bronson, Charlette (NIH/NIA) [E];Burrus-Shaw, Cyndi (NIH/OD) [E];Clark, Katie;Craver, Stephanie (NIH/NIAMS) [E];Doswell, Greta (NIH/OD) [E];Edmonds, Pamela;Yuliya Ilchyk;McManus, Ayanna (NIH/OD) [E];Melencio, Cheryl (FNIH) [T];Meltzer, Sherry (NIH/NIAMS) [E];Morgan, Emily (FNIH) [T];Tanya Murza;NIHDirectorMeetings;Poniente, Josefina;Poole, Charlene (NIH/NIDDK) [C];Protasiewicz, Ann;Schulke, Hilda (NIH/OD) [E];Sheehan, Joan (NIH/NIA) [E];Simon, Dina (NIH/OD) [C];Walker, Paula (NIH/NINDS) [E];Wood, Gretchen (NIH/OD) [E];Zander, Debra;Burkhardt, Carolyn;Choisnet, Tracey;Corsini, Linda;Hays, Marian;Jacquet, Catherine;Jones, Kim;Koch, Kellie;LaViolette, Rita;Ligon, Sharnell (CDER) (FDA/CDER);Perala, Mie;Profrock, Kathy;Schuster, Donna;Sultani, Tila
Subject: New version of the AMP Type 2 Diabetes Portal -- Please have a look!

Dear AMP Extended Executive Committee Members,

In advance of Friday's AMP Extended EC teleconference, and on behalf of the AMP T2D Steering Committee, we invite you to have a look at the newly updated **Type 2 Diabetes Knowledge Portal**.

As you know, the portal has been developed as part of the Accelerating Medicines Partnership (AMP) Type 2 Diabetes (T2D) program. Central to the AMP-T2D program is the assembly of global human T2D and diabetes complications genotype and phenotype data in conjunction with innovative analytic tools that enable identification and validation of novel targets for therapeutic development. Since the knowledge portal was released in 2015, the scale of genotype and phenotype data and the range of analytic and data visualization tools have advanced markedly to increase the impact of the portal for target evaluation.

We encourage you to explore the latest version of the knowledge portal and welcome feedback on your experience. **The portal web address is as follows:**

http://www.type2diabetesgenetics.org/home/portalHome

Thank you,

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health

Cc: Melissa Thomas, Lilly
Phil Smith, NIDDK
Nicole Spear, FNIH

From: Wholley, David (FNIH) [T]
Sent: Thu, 18 Aug 2016 11:30:42 -0400
To: Collins, Francis (NIH/OD) [E]
Subject: NIH funding for PACT design

Hi Francis—I have not heard anything on the status of this and of course it drive our funding outreach. Just wondering if you have anything to update me on about this. Thanks David

From: Wholley, David (FNIH) [T]
Sent: Wed, 21 Sep 2016 14:04:36 -0400
To: Collins, Francis (NIH/OD) [E]
Subject: NIH funds for PACT

Dear Francis,

I am pleased to formally let you know that today we received from your office the $150,000 addition to NIH's annual contribution to FNIH intended to be used for the Partnership for Accelerating Cancer Therapies (PACT) and have begun putting it to immediate use to design the partnership in coordination with the Cancer Moonshot efforts.

Regards,

David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
9650 Rockville Pike | Bethesda, MD 20814 | **fnih.org**
Direct (301) 594-6343 | dwholley@fnih.org



For 13 consecutive years, Charity Navigator has rated the FNIH as an organization that *exceeds industry standards.*

From: Wholley, David (FNIH) [T]
Sent: Sun, 7 Aug 2016 11:13:10 -0400
To: Collins, Francis (NIH/OD) [E]
Cc: Hudson, Kathy (NIH/OD) [E]
Subject: NIH support for PACT Design Phase

Hi Francis:

In our last PACT meeting with you a few weeks ago you said NIH would be able to (b) (4) In speaking with our finance folks, however, the question was raised of how NIH would actually get those funds to us, given the existing restrictions on how you give us money. Talking this over internally, I think there are two possible approaches:

(b) (4)

Can you please let me know how you would like this to work, or have someone on your staff work with us to figure the mechanism out quickly (given the urgency of moving this forward), so we know what to put in the "ask" to the companies?

Thanks,
David

From: Wholley, David (FNIH) [T]
Sent: Wed, 14 Dec 2016 09:18:01 -0500
To: Collins, Francis (NIH/OD) [E]
Subject: FW: slides
Attachments: Slides for Walter.pptx

Does this look better? (Outside of the question mark in the header for the first slide...)

From: Koroshetz, Walter (NIH/NINDS) [E]
Sent: Wednesday, December 14, 2016 8:17 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Sutherland, Margaret (NIH/NINDS) [E]
(b) (6)
Subject: slides

Thanks. This looks good. I made a few more edits to simplify further.
walter

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

From: Wholley, David (FNIH) [T]
Sent: Tue, 13 Dec 2016 21:23:03 -0500
To: Collins, Francis (NIH/OD) [E];Koroshetz, Walter (NIH/NINDS) [E]
Cc: Sutherland, Margaret (NIH/NINDS) [E];Canet-Aviles, Rosa (FNIH) [T]
Subject: Fw: Technical proposal for Verily collaboration in AMP-PD

Hi Walter and Francis--OK, not exactly sure how large the commitment will be but based on the extensive back and forth to get to this point I would say (b) (4) Thanks to Marg and her team for their support in writing up a technical proposal that, I beleive, put us over the top with Verily.
Sent from my BlackBerry 10 smartphone.

From: William Marks (b) (6)
Sent: Tuesday, December 13, 2016 7:12 PM
To: Wholley, David (FNIH) [T]; Koroshetz, Walter (NIH/NINDS) [E]
Cc: Sutherland, Margaret (NIH/NINDS) [E]; Canet-Aviles, Rosa (FNIH) [T]
Subject: Re: Technical proposal for Verily collaboration in AMP-PD

David and Marg,
We at Verily are very interested in participating in AMP PD. I'd like to organize a call with our team and yours to solidify some of the high-level structural issues around the two options and also around the terms of an agreement. Looking at calendars, with the holidays and pre-scheduled travel, it looks like the first date that could work is January 13. Would that time frame work to have a follow-up discussion?
Thanks!
Bill

William J. Marks, Jr., MD, MS-HCM | 415-736-7580 | (b) (6)

verily

On Mon, Dec 12, 2016 at 7:12 AM, Wholley, David (FNIH) [T] <dwholley@fnih.org> wrote:

Thanks, Marg, for the additional clarification here. Bill, let us know if you need anything else to get to a decision on this internally. Thanks, David

From: Sutherland, Margaret (NIH/NINDS) [E]
Sent: Monday, December 12, 2016 10:09 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>; William Marks (b) (6)>
Cc: Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnih.org>
Subject: RE: Technical proposal for Verily collaboration in AMP-PD

Hi Bill and David,

We would want to start the infrastructure build in the 2nd to 3rd quarter of 2017. The PDBP DMR is currently working on management of the exome data, but will also be receiving human RNA seq data from a laser capture cell project NINDS funded through the PDBP (50 PD brains, 50 control brains), which is about 2 TB of data in January 2017. Discussing the infrastructure strategy early would be beneficial, as it will help to guide the direction and expectations for data acquisition and analysis. Marg

---

From: Wholley, David (FNIH) [T]
Sent: Saturday, December 10, 2016 8:22 PM
To: William Marks (b) (6)
Cc: Sutherland, Margaret (NIH/NINDS) [E] (b) (6); Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnih.org>
Subject: Re: Technical proposal for Verily collaboration in AMP-PD

Great to hear. AMP -PD would launch in 2017; I expect it may take until early 3Q at least to get some of the grants approved but I believe there is a fair amount that can be started before then, including some of the technology platform work to which we are hoping you will contribute. Am asking Marg to confirm via copy to her. Thanks, David

Sent from my BlackBerry 10 smartphone.

From: William Marks

Sent: Saturday, December 10, 2016 2:02 PM

To: Wholley, David (FNIH) [T]

Cc: Sutherland, Margaret (NIH/NINDS) [E]; Canet-Aviles, Rosa (FNIH) [T]

Subject: Re: Technical proposal for Verily collaboration in AMP-PD

Hi, David, Margaret, and Rosa.

I have been socializing this proposal throughout Verily with favorable reaction and have meeting with our CEO scheduled for this coming week.

For purposes of planning, can you tell me when the actual new "work" by Verily would begin? When would "Year 1" of the initiative actually be expected to begin?

Thanks--more soon.

Bill

William J. Marks, Jr., MD, MS-HCM | 415-736-7580 | (b) (6)

Verily

On Mon, Nov 28, 2016 at 1:29 PM, Wholley, David (FNIH) [T] <dwholley@fnih.org> wrote:

Dear Bill:

We have not heard back from you yet regarding Verily's interest in joining the AMP AD partnership, but it occurred to me that perhaps you would find useful a somewhat more technical explanation of the knowledge portal platform we envision for AMP-PD and how Verily could contribute "in-kind" to support it. I therefore asked our colleagues at NINDS to put together a technical overview of the planned platform and a few sentences as to how Verily support might work. This is described in the attached .pdf document; the accompanying Excel file contains a further description of the datasets involved and their estimated storage and analysis requirements.

I hope this proves helpful as you move forward with a decision on supporting the partnership. Please don't hesitate to send any additional questions about this our way, and we'll do our best to get them answered promptly. We look forward to hearing back from you soon.

David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
9650 Rockville Pike | Bethesda, MD 20814 | **fnih.org**

Direct (301) 594-6343 | dwholley@fnih.org

FNIH
Foundation for the
National Institutes of Health

For 13 consecutive years, Charity Navigator has rated the FNIH as an organization that *exceeds industry standards.*

From: Wholley, David (FNIH) [T]
Sent: Wed, 26 Oct 2016 15:55:25 -0400
To: Collins, Francis (NIH/OD) [E]
Cc: Melencio, Cheryl (FNIH) [T];Wood, Gretchen (NIH/OD) [E];Boskent, Celeste (NIH/OD) [E];McManus, Ayanna (NIH/OD) [E];Di Mantova, Emma (NIH/OD) [E]
Subject: mail for AMP EC cancellation

Francis—
Sorry to bother you but before I send out the cancellation note below I wanted to ask about the December Extended EC call, which is currently scheduled for 8-9:30 AM EST on Friday, December 16. Knowing what we now know, it is likely Francis and Jan would have to miss the first hour of the call. If we try to move it to 7AM, they'd miss the last half hour (which might be worse). How would you like to play this one? As a reminder we sought the early hour for this in particular to accommodate our European-based colleagues. Thanks, David

Dear AMP EC members and SC co-chairs:

It appears some of our AMP Executive Committee members now have standing conflicts that prevent them from making our standard 8AM time slot on Fridays once a month. **Since it appears we will be missing some key participants for this week's meeting we have decided to cancel this Friday's AMP Executive Committee call, scheduled for 8:00 AM EDT.** We will send around a summary of where we stand on AMP in its stead, and reconvene the EC in November.

In the longer term we are proposing changing the timing and frequency of the calls. It has been proposed that we change the time of the next scheduled call on Friday, November 18 from 8:AM to 7:00 AM EDT, and then reduce the frequency of the EC calls to once every two months thereafter (i.e., 7AM on the last Friday of January, March, May, and so forth).

Is this possible? Can you please respond with your revised availability to Cheryl Melencio (cmelencio@fnih.org)? Thank you for your understanding and commitment.

Regards,
David Wholley

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
9650 Rockville Pike | Bethesda, MD 20814 | **fnih.org**
Direct (301) 594-6343 | dwholley@fnih.org



For 13 consecutive years, Charity Navigator has rated the FNIH as an organization that *exceeds industry standards.*

From: Wholley, David (FNIH) [T]
Sent: Fri, 21 Oct 2016 09:25:22 -0400
To: Collins, Francis (NIH/OD) [E]
Cc: Wood, Gretchen (NIH/OD) [E];Di Mantova, Emma (NIH/OD) [E];Boskent, Celeste (NIH/OD) [E];Gadbois, Ellen (NIH/OD) [E];Melencio, Cheryl (FNIH) [T]
Subject: Re: AMP Executive Committee Telecon -- October 28, 2016

FYI, Francis. Please let me know what you'd like to do. Thanks
Sent from my BlackBerry 10 smartphone.

From: Melencio, Cheryl (FNIH) [T]
Sent: Friday, October 21, 2016 8:24 AM
To: Wholley, David (FNIH) [T]
Subject: FW: AMP Executive Committee Telecon -- October 28, 2016

fyi

From: Protasiewicz, Ann [mailto:Ann.Protasiewicz@pfizer.com]
Sent: Thursday, October 20, 2016 7:43 PM
To: Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>
Subject: RE: AMP Executive Committee Telecon -- October 28, 2016

Hi Cheryl,

Mikael is scheduled to be at the airport the morning of October 28. He will try to dial into part of the AMP call, but it may be difficult as it will be at the time he is scheduled to check in. Morten Sogaard is available to participate for the duration of the call. Mikael would like for him to do so, if permissible.

Please let me know, once you have check with David, if Morten will be permitted to participate.

Regards,

Ann

Ann Martin Protasiewicz
Executive Assistant to
Mikael Dolsten, President
Worldwide Research and Development
Pfizer Inc.
235 East 42nd Street, Floor 22
New York, NY 10017
212-733-5859 (Office)
(b) (6) (Mobile)
E-Mail – ann.protasiewicz@pfizer.com

From: Melencio, Cheryl (FNIH) [T] [mailto:cmelencio@fnih.org]
Sent: Wednesday, October 12, 2016 11:41 AM
To: Protasiewicz, Ann
Subject: RE: AMP Executive Committee Telecon -- October 28, 2016

I am checking with David.

Will let you know.

Cheryl

From: Protasiewicz, Ann [mailto:Ann.Protasiewicz@pfizer.com]
Sent: Wednesday, October 12, 2016 10:12 AM
To: Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>
Subject: RE: AMP Executive Committee Telecon -- October 28, 2016

Hi Cheryl,

Mikael is now scheduled to travel on Friday, October 28. If need be, would it be permissible for Morten Sogaard to participate in Mikael's stead, if he is available?

Ann

Ann Martin Protasiewicz
Executive Assistant to
Mikael Dolsten, President
Worldwide Research and Development
Pfizer Inc.
235 East 42nd Street, Floor 22
New York, NY 10017
212-733-5859 (Office)
(b) (6) (Mobile)
E-Mail – ann.protasiewicz@pfizer.com

From: Melencio, Cheryl (FNIH) [T] [mailto:cmelencio@fnih.org]
Sent: Thursday, October 6, 2016 1:24 PM
To: Buckholtz, Neil (NIH/NIA) [C]; Carter, Robert (NIH/NIAMS) [E]; Cuss, Francis; Decker, Mike; Dolsten, Mikael; Gadbois, Ellen (NIH/OD) [E]; Hodes, Richard (NIH/NIA) [E]; Hodge, Martin; Katz, Stephen I. (NIH/NIAMS) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Lea, Allison (NIH/OD) [C]; Lifton, Richard; Lundberg, Jan; Paltoo, Dina (NIH/OD) [E]; Rodgers, Griffin (NIH/NIDDK) [E]; Ryan, Laurie (NIH/NIA) [E]; Serrate-Sztein, Susana (NIH/NIAMS) [E]; Smith, Philip (NIH/NIDDK) [E]; Stein, Peter; Sutherland, Margaret (NIH/NINDS) [E]; Terry, Sharon MA
Cc: Boskent, Celeste (NIH/OD) [E]; Bronson, Charlette (NIH/NIA) [E]; Cappello, Elizabeth; Clark, Katie; Craver, Stephanie (NIH/NIAMS) [E]; Edmonds, Pamela; Gwaldis, Janice; Yuliya Ilchyk; Kent, Bridgett (NIH/NIDDK) [C]; Meltzer, Sherry (NIH/NIAMS) [E]; Tanya Murza; Poole, Charlene (NIH/NIDDK) [E]; Protasiewicz, Ann; Sheehan, Joan (NIH/NIA) [E]; Walker, Paula (NIH/NINDS) [E]; Wilkerson, Anita D. (NIH/NIDDK) [E]; Zander, Debra
Subject: AMP Executive Committee Telecon -- October 28, 2016

Good afternoon,

The next call of the AMP Executive Committee is Friday, October 28 from 8 – 9 a.m. Eastern time. Please confirm your attendance.

Thank you

Cheryl Melencio

Cheryl Melencio
Executive Assistant, Research Partnerships
Foundation for the National Institutes of Health
9650 Rockville Pike | Bethesda, MD 20814 | www.fnih.org
Direct (301) 402-4970 | Fax (301) 480-2752

Combined Federal Campaign (CFC) #29165

For 13 consecutive years, Charity Navigator has rated the FNIH as an organization that *exceeds industry standards.*



To facilitate conservation of earth's precious natural resources please consider the environment before printing this email.
Confidentiality Notice: *Information contained in this e-mail and attachments may be legally privileged and confidential. If you are not an intended recipient, you are hereby notified that dissemination, distribution or copying this e-mail and attachments is strictly prohibited; please delete the e-mail and attachments immediately.*

From: Wholley, David (FNIH) [T]
Sent: Mon, 24 Oct 2016 09:20:53 -0400
To: Collins, Francis (NIH/OD) [E]
Cc: Wood, Gretchen (NIH/OD) [E];Di Mantova, Emma (NIH/OD) [E];Boskent, Celeste (NIH/OD) [E];Gadbois, Ellen (NIH/OD) [E];Melencio, Cheryl (FNIH) [T]
Subject: RE: AMP Executive Committee Telecon -- October 28, 2016

Not good. Both Cuss and Lundberg had originally accepted, and have now declined. Next meeting is Friday, November 18. Lundberg has already said he cannot make that one, but Dolsten and Cuss have accepted it. Not that that guarantees anything…

Please let me know what you'd like to do. We have nothing too pressing right now, having resolved the RA/SLE milestone for now (we have confirmed votes 'yes" from all the partners).

David

From: Collins, Francis (NIH/OD) [E]
Sent: Friday, October 21, 2016 8:31 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Wood, Gretchen (NIH/OD) [E] (b) (6); Di Mantova, Emma (NIH/OD) [E] (b) (6)>; Boskent, Celeste (NIH/OD) [E] (b) (6); Gadbois, Ellen (NIH/OD) [E] (b) (6); Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>
Subject: RE: AMP Executive Committee Telecon -- October 28, 2016

How's the rest of the attendance?

From: Wholley, David (FNIH) [T]
Sent: Friday, October 21, 2016 9:25 AM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Wood, Gretchen (NIH/OD) [E] (b) (6); Di Mantova, Emma (NIH/OD) [E] (b) (6); Boskent, Celeste (NIH/OD) [E] (b) (6); Gadbois, Ellen (NIH/OD) [E] (b) (6); Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>
Subject: Re: AMP Executive Committee Telecon -- October 28, 2016

FYI, Francis. Please let me know what you'd like to do. Thanks

Sent from my BlackBerry 10 smartphone.

From: Melencio, Cheryl (FNIH) [T]
Sent: Friday, October 21, 2016 8:24 AM
To: Wholley, David (FNIH) [T]
Subject: FW: AMP Executive Committee Telecon -- October 28, 2016

fyi

From: Protasiewicz, Ann [mailto:Ann.Protasiewicz@pfizer.com]
Sent: Thursday, October 20, 2016 7:43 PM

To: Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>
Subject: RE: AMP Executive Committee Telecon -- October 28, 2016

Hi Cheryl,

Mikael is scheduled to be at the airport the morning of October 28. He will try to dial into part of the AMP call, but it may be difficult as it will be at the time he is scheduled to check in. Morten Sogaard is available to participate for the duration of the call. Mikael would like for him to do so, if permissible.

Please let me know, once you have check with David, if Morten will be permitted to participate.

Regards,

Ann

Ann Martin Protasiewicz
Executive Assistant to
Mikael Dolsten, President
Worldwide Research and Development
Pfizer Inc.
235 East 42nd Street, Floor 22
New York, NY 10017
212-733-5859 (Office)
(b) (6) (Mobile)
E-Mail – ann.protasiewicz@pfizer.com

From: Melencio, Cheryl (FNIH) [T] [mailto:cmelencio@fnih.org]
Sent: Wednesday, October 12, 2016 11:41 AM
To: Protasiewicz, Ann
Subject: RE: AMP Executive Committee Telecon -- October 28, 2016

I am checking with David.

Will let you know.

Cheryl

From: Protasiewicz, Ann [mailto:Ann.Protasiewicz@pfizer.com]
Sent: Wednesday, October 12, 2016 10:12 AM
To: Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>
Subject: RE: AMP Executive Committee Telecon -- October 28, 2016

Hi Cheryl,

Mikael is now scheduled to travel on Friday, October 28. If need be, would it be permissible for Morten Sogaard to participate in Mikael's stead, if he is available?

Ann

Ann Martin Protasiewicz
Executive Assistant to
Mikael Dolsten, President
Worldwide Research and Development
Pfizer Inc.
235 East 42nd Street, Floor 22
New York, NY 10017
212-733-5859 (Office)
(b) (6) (Mobile)
E-Mail – ann.protasiewicz@pfizer.com

From: Melencio, Cheryl (FNIH) [T] [mailto:cmelencio@fnih.org]
Sent: Thursday, October 6, 2016 1:24 PM
To: Buckholtz, Neil (NIH/NIA) [C]; Carter, Robert (NIH/NIAMS) [E]; Cuss, Francis; Decker, Mike; Dolsten, Mikael; Gadbois, Ellen (NIH/OD) [E]; Hodes, Richard (NIH/NIA) [E]; Hodge, Martin; Katz, Stephen I. (NIH/NIAMS) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Lea, Allison (NIH/OD) [C]; Lifton, Richard; Lundberg, Jan; Paltoo, Dina (NIH/OD) [E]; Rodgers, Griffin (NIH/NIDDK) [E]; Ryan, Laurie (NIH/NIA) [E]; Serrate-Sztein, Susana (NIH/NIAMS) [E]; Smith, Philip (NIH/NIDDK) [E]; Stein, Peter; Sutherland, Margaret (NIH/NINDS) [E]; Terry, Sharon MA
Cc: Boskent, Celeste (NIH/OD) [E]; Bronson, Charlette (NIH/NIA) [E]; Cappello, Elizabeth; Clark, Katie; Craver, Stephanie (NIH/NIAMS) [E]; Edmonds, Pamela; Gwaldis, Janice; Yuliya Ilchyk; Kent, Bridgett (NIH/NIDDK) [C]; Meltzer, Sherry (NIH/NIAMS) [E]; Tanya Murza; Poole, Charlene (NIH/NIDDK) [E]; Protasiewicz, Ann; Sheehan, Joan (NIH/NIA) [E]; Walker, Paula (NIH/NINDS) [E]; Wilkerson, Anita D. (NIH/NIDDK) [E]; Zander, Debra
Subject: AMP Executive Committee Telecon -- October 28, 2016

Good afternoon,

The next call of the AMP Executive Committee is Friday, October 28 from 8 – 9 a.m. Eastern time. Please confirm your attendance.

Thank you

Cheryl Melencio

Cheryl Melencio
Executive Assistant, Research Partnerships
Foundation for the National Institutes of Health
9650 Rockville Pike | Bethesda, MD 20814 | www.fnih.org
Direct (301) 402-4970 | Fax (301) 480-2752

Combined Federal Campaign (CFC) #29165
For 13 consecutive years, Charity Navigator has rated the FNIH as an organization that *exceeds industry standards.*

FNIH
Foundation for the National Institutes of Health

To facilitate conservation of earth's precious natural resources please consider the environment before printing this email.
Confidentiality Notice: *Information contained in this e-mail and attachments may be legally privileged and confidential. If you are not an intended recipient, you are hereby notified that dissemination, distribution or copying this e-mail and attachments is strictly prohibited; please delete the e-mail and attachments immediately.*

From: Wholley, David (FNIH) [T]
Sent: Wed, 21 Sep 2016 17:08:09 -0400
To: Collins, Francis (NIH/OD) [E]
Subject: RE: AMP Executive Committee Teleconference

Still say they are coming.

From: Collins, Francis (NIH/OD) [E]
Sent: Wednesday, September 21, 2016 4:48 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: RE: AMP Executive Committee Teleconference

Arg. What about Dolsten and Cuss?

From: Wholley, David (FNIH) [T]
Sent: Wednesday, September 21, 2016 10:01 AM
To: Collins, Francis (NIH/OD) [E]
Subject: FW: AMP Executive Committee Teleconference

FYI, this seems to be about the time we get this message...he was in confirmed status two weeks ago.

From: Melencio, Cheryl (FNIH) [T]
Sent: Wednesday, September 21, 2016 9:59 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: FW: AMP Executive Committee Teleconference

This just came in from Jan Lundberg's office.

-----Original Appointment-----
From: Pamela J Edmonds [mailto:edmonds_pamela_j@lilly.com] **On Behalf Of** Jan Lundberg
Sent: Wednesday, September 21, 2016 9:58 AM
To: Melencio, Cheryl (FNIH) [T]
Subject: Declined: AMP Executive Committee Teleconference
When: Friday, September 23, 2016 8:00 AM-9:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: ((b) (6) France: 0805 770 131 Participant Code: (b) (6) Moderator Code: (b) (6) Project Code: (b) (6)

Cheryl, Jan has a priority conflict and will now not be available to participate on the call.
Thanks, Pam

From: Wholley, David (FNIH) [T]
Sent: Sun, 11 Dec 2016 20:17:34 -0500
To: Collins, Francis (NIH/OD) [E]
Subject: RE: AMP Extended EC Dry Run slides

Very sorry. Perhaps because this is an old meeting invitation..I will get our admins on this. Thanks for catching this Francis.

From: Collins, Francis (NIH/OD) [E]
Sent: Sunday, December 11, 2016 7:08 PM
To: Tabak, Lawrence (NIH/OD) [E] <(b) (6)
Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: FW: AMP Extended EC Dry Run slides

Hi Larry,

See below and attached for tomorrow's dry run of the AMP Extended Executive Committee meeting. David, can you be sure to include Larry in this e-mail list?

FC

From: Wholley, David (FNIH) [T]
Sent: Sunday, December 11, 2016 11:14 AM
To: Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Collins, Francis (NIH/OD) [E] (b) (6)>; Dolsten, Mikael <mikael.dolsten@pfizer.com>; Hoffmann, Steve (FNIH) [T] <shoffmann@fnih.org>; Spear, Nicole (FNIH) [T] <nspear@fnih.org>; Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnih.org>; Cuss, Francis <francis.cuss@bms.com>; Lundberg, Jan <lundberg_jan@lilly.com>; Carter, Robert (NIH/NIAMS) [E] (b) (6); Hodge, Martin <martin.hodge@pfizer.com>; Ryan, Laurie (NIH/NIA) [E] (b) (6); Decker, Mike <michael.w.decker@abbvie.com>; Smith, Philip (NIH/NIDDK) [E] (b) (6); Gadbois, Ellen (NIH/OD) [E] (b) (6)>; Lea, Allison (NIH/OD) [E] (b) (6); Hudson, Kathy (NIH/OD) [E] (b) (6)>; Arrowchis, Leeanna (NIH/NIDDK) [C] (b) (6) Zander, Debra <debra.zander@bms.com>; Edmonds, Pamela <edmonds_pamela_j@lilly.com>; Protasiewicz, Ann <ann.protasiewicz@pfizer.com>; Boskent, Celeste (NIH/OD) [E] (b) (6); Doswell, Greta (NIH/OD) [E] (b) (6); Di Mantova, Emma (NIH/OD) [E] (b) (6); Morgan, Emily (FNIH) [T] <emorgan@fnih.org>; NIHDirectorMeetings <NIHDirectorMeetings@mail.nih.gov>; Craver, Stephanie (NIH/NIAMS) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Sutherland, Margaret (NIH/NINDS) [E]

(b) (6); Whitaker, Sanya (FNIH) [T] <swhitaker@fnih.org>; Wood, Gretchen (NIH/OD) [E] (b) (6); thomas_melissa_k@lilly.com
Subject: AMP Extended EC Dry Run slides

Dear AMP EC members and SC co-chairs: Please find attached the slides for our run-through tomorrow afternoon of the AMP Extended EC meeting, along with the minutes from the last EEC meeting in June. As a reminder logistics are copied below. Look forward to our discussion. David

When: Monday, December 12, 2016 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: (b) (6) Participant code: (b) (6)# Moderator code: (b) (6)# Project Code (b) (6)

In preparation for the December 16 AMP Extended EC Telecon

<< File: AMP Ext EC Slides Dec 16 2016 DRAFT.pptx >> << File: 2016_06_27_AMP EEC telecon minutes final draft.docx >>

From: Wholley, David (FNIH) [T]
Sent: Mon, 12 Dec 2016 10:24:52 -0500
To: Melencio, Cheryl (FNIH) [T];Collins, Francis (NIH/OD) [E];Dolsten, Mikael;Hoffmann, Steve (FNIH) [T];Spear, Nicole (FNIH) [T];Canet-Aviles, Rosa (FNIH) [T];Cuss, Francis;Lundberg, Jan;Carter, Robert (NIH/NIAMS) [E];Hodge, Martin;Ryan, Laurie (NIH/NIA) [E];Decker, Mike;Smith, Philip (NIH/NIDDK) [E];Gadbois, Ellen (NIH/OD) [E];Lea, Allison (NIH/OD) [E];Hudson, Kathy (NIH/OD) [E];Arrowchis, Leeanna (NIH/NIDDK) [C];Zander, Debra;Edmonds, Pamela;Protasiewicz, Ann;Boskent, Celeste (NIH/OD) [E];Doswell, Greta (NIH/OD) [E];Di Mantova, Emma (NIH/OD) [E];Morgan, Emily (FNIH) [T];NIHDirectorMeetings;Craver, Stephanie (NIH/NIAMS) [E];Koroshetz, Walter (NIH/NINDS) [E];Sutherland, Margaret (NIH/NINDS) [E];Whitaker, Sanya (FNIH) [T];Wood, Gretchen (NIH/OD) [E];thomas_melissa_k@lilly.com;Tabak, Lawrence (NIH/OD) [E]
Subject: RE: AMP Extended EC Dry Run slides

Please just note: there was a typo on slide 35 (2D should read T2D), and slides 41 and 42 are duplicates. These have been corrected already in the master slide set. Thanks, David

From: Wholley, David (FNIH) [T]
Sent: Mon, 19 Dec 2016 20:13:06 -0500
To: Collins, Francis (NIH/OD) [E]
Subject: Re: AMP Parkinson's slide

Francis: I am not sure that is what the slide literally says or is intended to say. (b) (4)

(b) (4)

I guess I also see the 50/50 proposition as a useful construct rather than a literal rule. (b) (4)

(b) (4)

(b) (4) There are other examples:
50/50 seems to be somewhat in the eye of the beholder.

Is there a particular situation that is prompting your question? I am glad as always to speak further by phone on this at your convenience.

David
Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Monday, December 19, 2016 6:46 PM
To: Wholley, David (FNIH) [T]
Cc: Gadbois, Ellen (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]
Subject: FW: AMP Parkinson's slide

Hi David,

One question from last Friday's EEC discussion: I was surprised to see on Slide 41 (attached and below) that (b) (4)

Was that intentional? Can you clarify?

Francis


(b) (4)

From: Wholley, David (FNIH) [T]
Sent: Mon, 19 Dec 2016 23:00:49 -0500
To: Collins, Francis (NIH/OD) [E]
Cc: Gadbois, Ellen (NIH/OD) [E];Wolinetz, Carrie (NIH/OD) [E]
Subject: Re: AMP Parkinson's slide

I've heard no complaints. Thanks for the heads up
Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Monday, December 19, 2016 8:42 PM
To: Wholley, David (FNIH) [T]
Cc: Gadbois, Ellen (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]
Subject: RE: AMP Parkinson's slide

Hi David,

No particular situation, just the slide itself – where it seemed odd to me for NIH to be (b) (4) But I agree this is not the issue right now. If you've not heard any rumbling from pharmas about this, we can just let it go by.

Francis

From: Wholley, David (FNIH) [T]
Sent: Monday, December 19, 2016 8:13 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Subject: Re: AMP Parkinson's slide

Francis: I am not sure that is what the slide literally says or is intended to say. (b) (4)
(b) (4)

I guess I also see the 50/50 proposition as a useful construct rather than a literal rule. (b) (4)
(b) (4)
(b) (4) There are other examples: 50/50 seems to be somewhat in the eye of the beholder.

Is there a particular situation that is prompting your question? I am glad as always to speak further by phone on this at your convenience.

David
Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Monday, December 19, 2016 6:46 PM
To: Wholley, David (FNIH) [T]
Cc: Gadbois, Ellen (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]
Subject: FW: AMP Parkinson's slide

Hi David,

One question from last Friday's EEC discussion: I was surprised to see on Slide 41 (attached and below) that [redacted] (b) (4) Was that intentional? Can you clarify?

Francis


(b) (4)

From: Wholley, David (FNIH) [T]
Sent: Fri, 16 Dec 2016 07:51:46 -0500
To: Collins, Francis (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Gadbois, Ellen (NIH/OD) [E]
Subject: RE: AMP this morning

Darn, did not see this will be running the webex from FNIH. Sorry I will miss you.

From: Collins, Francis (NIH/OD) [E]
Sent: Friday, December 16, 2016 5:51 AM
To: Tabak, Lawrence (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Gadbois, Ellen (NIH/OD) [E] (b) (6)
Subject: AMP this morning

Turns out I will be in Bldg 1 by 8 AM, so feel free to join me in 1/116 or 1/126 for the AMP call, if that's convenient for you.

From: Wholley, David (FNIH) [T]
Sent: Fri, 16 Dec 2016 08:17:08 -0500
To: Collins, Francis (NIH/OD) [E]
Subject: Re: AMP this morning

Yes! I thought that was the plan. Great job by the way...though I noticed you did not say anything about keeping your lab at NIH and attending the calls. I trust that has not changed? Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Friday, December 16, 2016 7:54 AM
To: Wholley, David (FNIH) [T]
Subject: RE: AMP this morning

Should I say something to the EEC about Larry Tabak's joining us?

From: Wholley, David (FNIH) [T]
Sent: Friday, December 16, 2016 7:52 AM
To: Collins, Francis (NIH/OD) [E] (b) (6) Tabak, Lawrence (NIH/OD) [E] (b) (6); Gadbois, Ellen (NIH/OD) [E] (b) (6)
Subject: RE: AMP this morning

Darn, did not see this will be running the webex from FNIH. Sorry I will miss you.

From: Collins, Francis (NIH/OD) [E]
Sent: Friday, December 16, 2016 5:51 AM
To: Tabak, Lawrence (NIH/OD) [E] (b) (6) Wholley, David (FNIH) [T] <dwholley@fnih.org>; Gadbois, Ellen (NIH/OD) [E] (b) (6)>
Subject: AMP this morning

Turns out I will be in Bldg 1 by 8 AM, so feel free to join me in 1/116 or 1/126 for the AMP call, if that's convenient for you.

From: Wholley, David (FNIH) [T]
Sent: Fri, 12 Aug 2016 14:54:47 -0400
To: Collins, Francis (NIH/OD) [E]
Subject: PACT email to Rob Califf

Email to Rob Califf to invite FDA to participate in PACT Workgroups:
CC: David Wholley, Stacey Adam, Kathy Hudson, Doug Lowy, Jim Doroshow, Rebecca Baker, Laura Rosema

Hi Rob,
I am writing to ask how FDA could be more formally involved in the Partnership for Accelerating Cancer Therapies (PACT) that we have been working on with the White House and with industry and cancer non-profits over the last few months. Since the initial calls about the partnership (in which I know you participated) and the Cancer Moonshot Summit (at which the Vice-President mentioned PACT) we have had further discussions with NCI leadership and some industry oncology leads that have winnowed the original four focus areas we'd been discussing down to two:

1. **Identification and validation of biomarkers for response and resistance to cancer immunotherapies**
2. **Establishment of a platform for selecting and testing combination therapies**

(Support for the other two areas, disease modeling and rare cancers, was confined to relatively fewer partners and could be, we felt, addressed as part of our focus on the first two areas).

I have also meanwhile asked the Foundation for the NIH to take over the effort to design specific research agendas for the two lead focus areas, using a process similar to what we used to develop the Accelerating Medicines Partnership. FNIH has begun to establish two workgroups--with pharma, NIH and academic researchers represented in each--to develop a "white paper" level description of potential research agenda as a tool for confirming funding and participation. Since both of the PACT focus areas have strong regulatory science implications and are obviously relevant to FDA's mission, I would appreciate it if you would consider nominating at least one or two scientists from FDA to serve on these workgroups. My understanding is that the initial time commitment for this would consist of 3-4 teleconferences (~2 hours each) and 2 in-person meetings (~1.5 days each) beginning in late August and concluding just before Thanksgiving in November. The idea is to have initial consensus around research agendas and willingness of specific partners to fund by December, with a PACT launch in mid-2017.

Please let me know your thoughts, and don't hesitate to reach out either to me or to David Wholley at FNIH with any questions.

Kind regards,

Francis S. Collins, M.D., Ph.D.
Director, NIH

From: Wholley, David (FNIH) [T]
Sent: Thu, 1 Sep 2016 15:36:46 -0400
To: Collins, Francis (NIH/OD) [E]
Subject: PACT Working Group Member Calls - (b) (5)

Hi Francis:

Things are going quite well with the first focus group in PACT (biomarkers), co-chaired by Alex Hoos of GSK and Helen Chen at NCI. We have had several calls with the co-chairs and have begun drafting up an outline of a white paper to feed into a planned face to face on September 22. For Focus Group 2 (combination therapy trials), which is co-chaired by Jeff Engelman of Novartis and Percy Ivy of NCI, however, while we have had very good input from Percy and have had Jeff on one introductory telecon, we are tearing our hair out trying to get any sort of availability from Jeff for further teleconferences, much less the face to face. I have written to him myself but he appears to be out (on vacation perhaps) until Tuesday 9/6, and his assistant has not been able to be of much help. (We also now have, by the way, positive responses on contributions to and participation in the PACT design effort from seven companies, (b) (4)

I am conscious that Jeff is involved because of your relationship with and request to Jay Bradner. But this is already a threat to schedule and I think it is time to either establish Jeff's ability to commit the necessary time to this effort, or regretfully seek another co-chair. How would you like to proceed?

Thanks, David

From: Caulfield, Anita [mailto:anita.caulfield@novartis.com]
Sent: Thursday, September 01, 2016 11:58 AM
To: Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Subject: Re: PACT Working Group Member Orientation Call - (b) (5)

Hi Stacy,

No worries. Jeff is not available on those dates, sorry. I can tell you that Jeff's next 2-hour opening is in the first week of October.

Thanks,
Anita

On Sep 1, 2016, at 11:45 AM, Adam, Stacey (FNIH) [T] <sadam@fnih.org> wrote:

Hi Anita,

I know you are likely tired of hearing from me. Could you please tell me if Jeff would be available for a 2 hour call at either of the following two times next week?

September 6th – 4-6pm

September 7th – 4-6pm

Thanks,
Stacey

Stacey J. Adam, Ph.D.
Scientific Program Manager, Cancer
Foundation for the National Institutes of Health
Direct (301) 435-8364 | Mobile (b) (6)

From: Adam, Stacey (FNIH) [T]
Sent: Wednesday, August 31, 2016 1:40 PM
To: Caulfield, Anita <anita.caulfield@novartis.com>
Subject: Re: PACT Working Group Member Orientation Call - (b) (5)

Hi Anita,

I am sorry to be a pain, but two questions.

Would you have time to fill out the Doodle poll for Jeff's availability today? Or send me his availability for a 2 hour call next week between Sep 6-9 via email? We are desperate to lock down a time for our first Working Group call, but we need Jeff's schedule to do so.

Also, my director wanted me to ask if there was a possibility of moving Jeff's meeting on Sep 22. This is a very important initiative for the White House Cancer Moonshot and we are on very tight timelines from the WH to get this finished and really need to have this first meeting in late September. Most members can do the 22, but we really need all of our chairs there. If this is possible, I am happy to discuss the need of the phone with you.

Thanks,
Stacey

Sent from my BlackBerry 10 smartphone.

From: Adam, Stacey (FNIH) [T]
Sent: Tuesday, August 30, 2016 4:18 PM
To: Caulfield, Anita
Subject: RE: PACT Working Group Member Orientation Call - (b) (5)

Thanks, Anita,

This was expected, but I wanted him to know they were taking place.

Also, have you had a chance to fill out the fixed Doodle poll link I sent yesterday? Or any thoughts on the availability document?

I know this is a lot, but any help you can provide would be most helpful.

Thanks,
Stacey

Stacey J. Adam, Ph.D.
Scientific Program Manager, Cancer
Foundation for the National Institutes of Health
Direct (301) 435-8364 | Mobile (b) (6)

-----Original Appointment-----
From: Caulfield, Anita [mailto:anita.caulfield@novartis.com] **On Behalf Of** Engelman, Jeffrey
Sent: Tuesday, August 30, 2016 4:13 PM
To: Adam, Stacey (FNIH) [T]
Subject: Tentative: PACT Working Group Member Orientation Call - (b) (5)
When: Thursday, September 01, 2016 2:30 PM-3:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Conference Line: (b) (6) Participant Code (b) (6) Moderator code: (b) (6) Project code: (b) (6)

Jeff is currently out of the office traveling and will not be able to participate in this call on 9/1.

From: Wholley, David (FNIH) [T]
Sent: Fri, 26 Aug 2016 16:06:04 -0400
To: Collins, Francis (NIH/OD) [E]
Cc: Adam, Stacey (FNIH) [T];Baker, Rebecca (NIH/OD) [E];Rosema, Laura (NIH/OD) [E];Wolf-Rodda, Julie (FNIH) [T];Donnelly, Meredith (FNIH) [T]
Subject: Progress on funding PACT design phase

Hi Francis:
Going into the weekend I thought you'd like to hear that so far we have pretty firm promises of support

(b) (4)

David

From: Wholley, David (FNIH) [T]
Sent: Thu, 8 Sep 2016 11:11:34 -0400
To: Collins, Francis (NIH/OD) [E]
Subject: RE: $ for PACT?

(b) (5)

(b) (5) Let me know if you have any additional questions.

David

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, September 08, 2016 11:09 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: $ for PACT?

Hi David,

(b) (5)

FC

From: Wholley, David (FNIH) [T]
Sent: Wed, 26 Oct 2016 13:25:17 -0400
To: Melencio, Cheryl (FNIH) [T];Collins, Francis (NIH/OD) [E];Gadbois, Ellen (NIH/OD) [E];Lea, Allison (NIH/OD) [C];NIHDirectorMeetings;Hudson, Kathy (NIH/OD) [E];Wood, Gretchen (NIH/OD) [E];Doswell, Greta (NIH/OD) [E];Boskent, Celeste (NIH/OD) [E];Di Mantova, Emma (NIH/OD) [E];McManus, Ayanna (NIH/OD) [E];Hoffmann, Steve (FNIH) [T];Spear, Nicole (FNIH) [T];Whitaker, Sanya (FNIH) [T];Canet-Aviles, Rosa (FNIH) [T];Morgan, Emily (FNIH) [T];Menetski, Joseph (FNIH) [T]
Subject: RE: AMP EC Pre-Call
Attachments: AMP EC Slides October 28, 2016 DRAFT.pptx, 2016-09-23_AMP_EC_Telecon_minutes_RLA.docx, Copy of AMP - EC Attendance for Oct28.xlsx
Importance: High

I am assuming we are going forward with our meeting Friday morning and with our pre-call at 2PM. Here are the materials. Sorry for the late note.

David

-----Original Appointment-----
From: Melencio, Cheryl (FNIH) [T]
Sent: Wednesday, October 12, 2016 4:47 PM
To: Melencio, Cheryl (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Lea, Allison (NIH/OD) [C]; NIHDirectorMeetings; Hudson, Kathy (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Doswell, Greta (NIH/OD) [E]; Boskent, Celeste (NIH/OD) [E]; Di Mantova, Emma (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Wholley, David (FNIH) [T]; Hoffmann, Steve (FNIH) [T]; Spear, Nicole (FNIH) [T]; Whitaker, Sanya (FNIH) [T]; Canet-Aviles, Rosa (FNIH) [T]; Morgan, Emily (FNIH) [T]; Menetski, Joseph (FNIH) [T]
Subject: AMP EC Pre-Call
When: Wednesday, October 26, 2016 2:00 PM-2:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: (b) (6) Participant code: (b) (6) Moderator code: (b) (6) Project code: (b) (6)

Accelerating Medicines PartnershipCore Executive Committee Meeting

28 October, 2016



FNIH
Foundation for the National Institutes of Health

(b) (4), (b) (5)

(b) (4), (b) (5)

Accelerating Medicines PartnershipAMP Parkinson's Disease(Program Development Update)

FNIH

Foundation for the National Institutes of Health

NIH - 001457



(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

Accelerating Medicines PartnershipAlzheimer's Disease

FNIH

Foundation for the National Institutes of Health

NIH - 001461



(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

AMP AD F2F Annual Meeting 2016

- (b) (5)



NIH - 001465

Accelerating Medicines PartnershipType 2 Diabetes

FNIH

Foundation for the
National Institutes of Health

NIH - 001466



(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

Accelerating Medicines PartnershipRA/SLE

FNIH

Foundation for the
National Institutes of Health

NIH - 001474



(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

Executive Committee

- **Next MeetingsAMP EC: Friday, November 18 from 8:00am – 9:00am Eastern US Time**

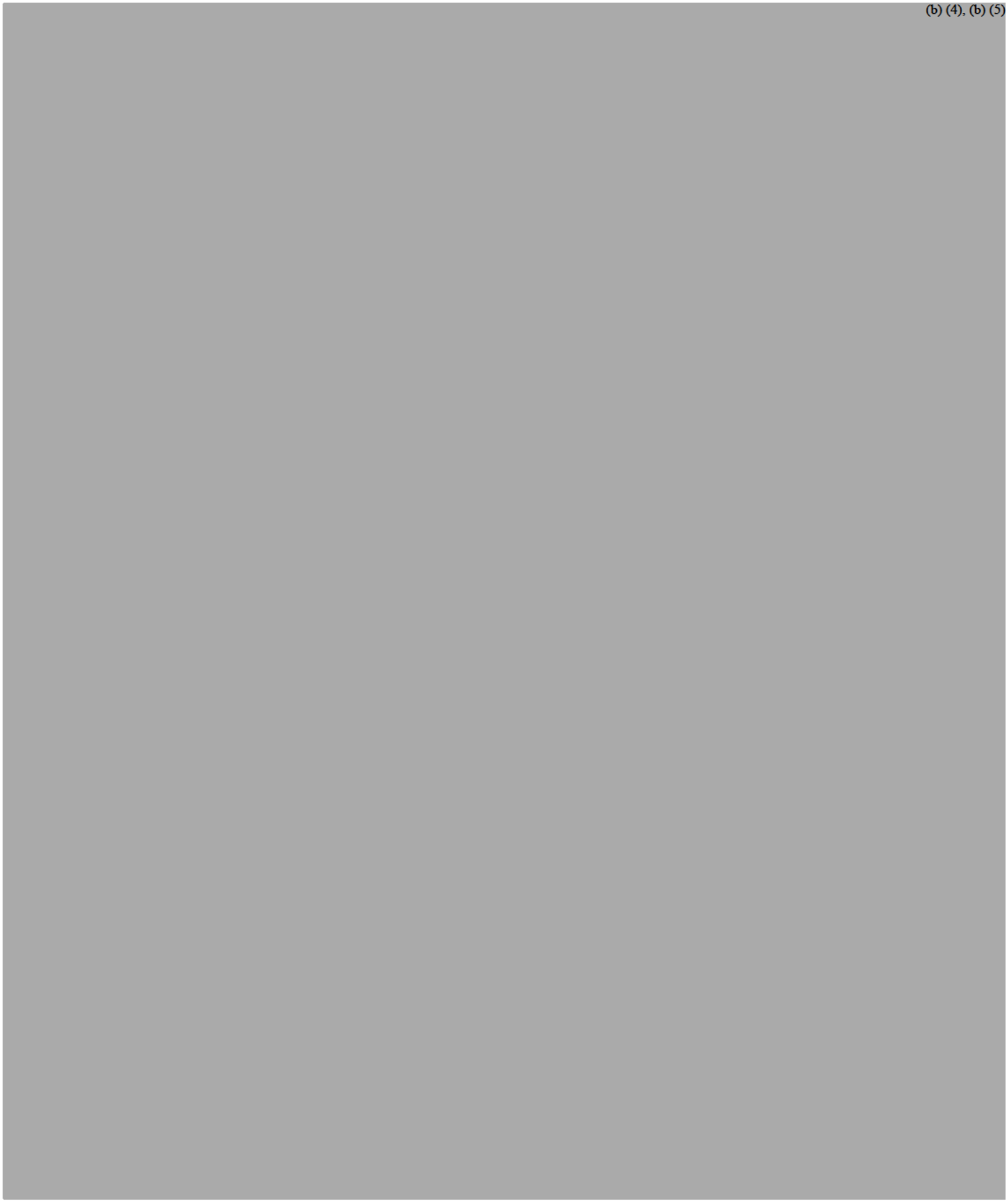
Foundation for the National Institutes of Health
Accelerating Medicines Partnership
Core Executive Committee
Teleconference Meeting Minutes
Friday, September 23, 2016
8:00 a.m.– 9:00 a.m. ET

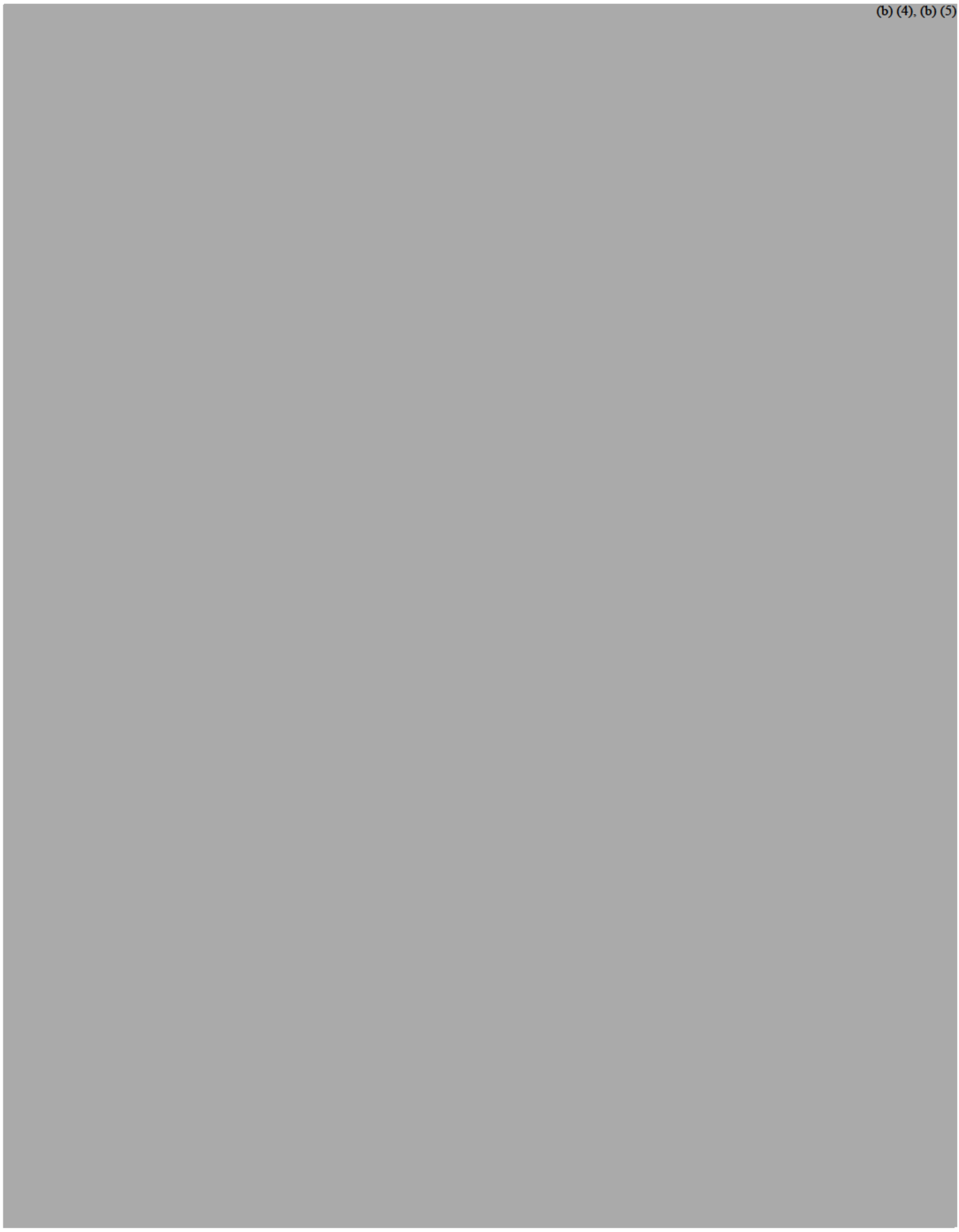
Participants:

Neil Buckholtz (NIH/NIA), Rosa Canet-Aviles (FNIH), Robert Carter (NIH/NIAMS), Francis Collins (NIH/OD), Francis Cuss (BMS), Michael Decker (AbbVie), Michael Dolsten (Pfizer), Ellen Gadbois (NIH/OD), Richard Hodes (NIH/NIA), Marty Hodge (Pfizer), Steve Hoffmann (FNIH), Steve Katz (NIH/NIAMS), Allison Lea (NIH/OD), Dina Paltoo (NIH/OD), Griffin Rodgers (NIH/NIDDK), Laurie Ryan (NIH/NIA),Clement Scherzer (Harvard Medical School), Philip Smith (NIH/NIDDK), Susana Serrate-Sztein (NIH/NIAMS), Philip Smith (NIH/NIDDK), Nicole Spear (FNIH), Peter Stein (Merck), David Stone (Merck), Margaret Sutherland (NINDS), Sanya Fanous-Whitaker (FNIH), David Wholley (FNIH)

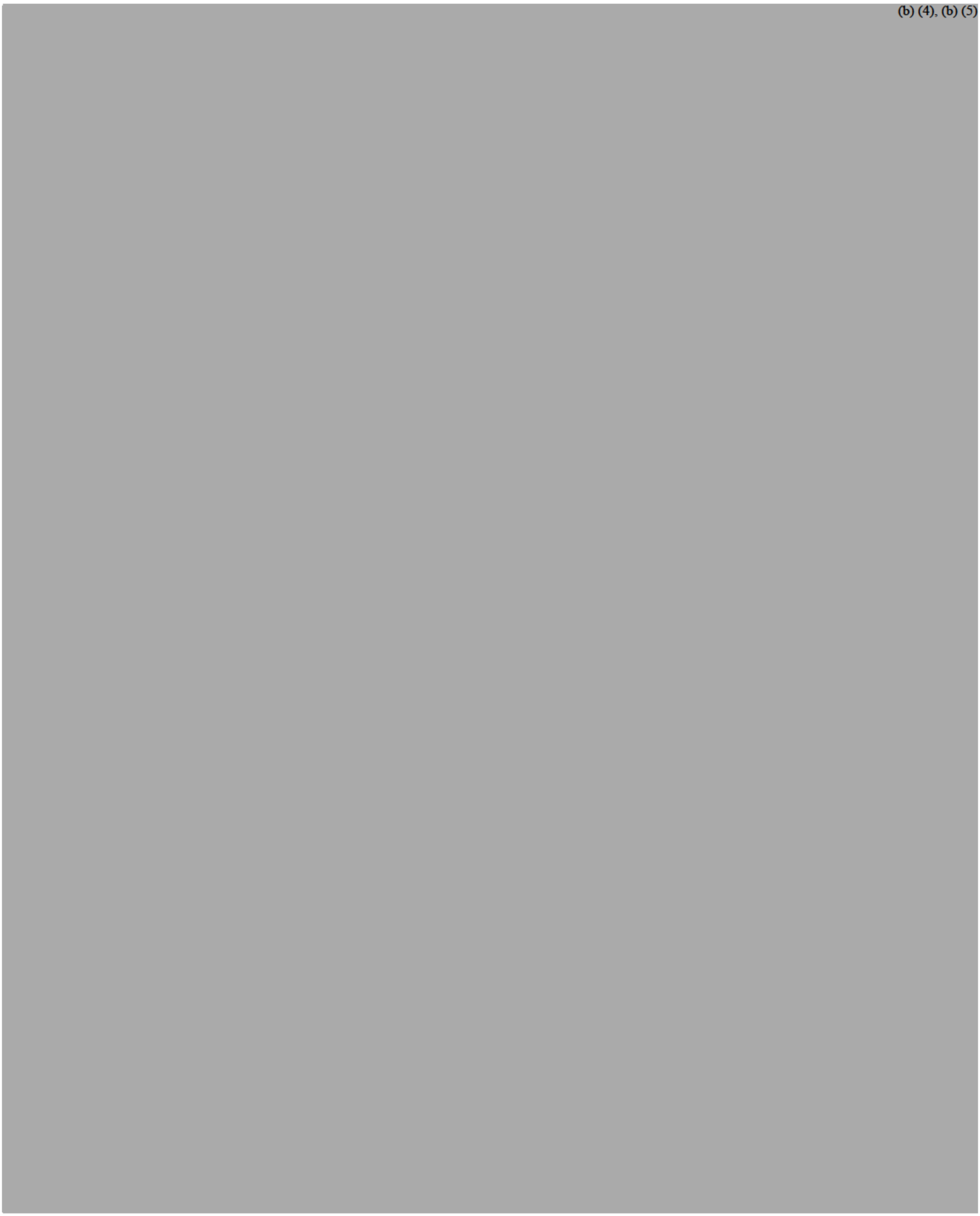
(b) (4), (b) (5)







(b) (4), (b) (5)



(b) (4), (b) (5)

Attendance for AMP EC -- 10/28/16

Name	Attendance	Response
Melencio, Cheryl (FNIH) [T]	Meeting Organizer	None
Buckholtz, Neil (NIH/NIA) [C]	Required Attendee	Accepted
Canet-Aviles, Rosa (FNIH) [T]	Required Attendee	Accepted
Carter, Robert (NIH/NIAMS) [E]	Required Attendee	Accepted
Collins, Francis (NIH/OD) [E]	Required Attendee	Accepted
Cuss, Francis	Required Attendee	Declined -- due to other commitments/had originally accepted
Decker, Mike	Required Attendee	Accepted
Dolsten, Mikael	Required Attendee	Declined has travel -- wants Morten Sogaard to attend [may make first 40 mins]
Gadbois, Ellen (NIH/OD) [E]	Required Attendee	Accepted
Hodes, Richard (NIH/NIA) [E]	Required Attendee	Accepted
Hodge, Martin	Required Attendee	Accepted
Hoffmann, Steve (FNIH) [T]	Required Attendee	Accepted
Hudson, Kathy (NIH/OD) [E]	Required Attendee	None
Katz, Stephen I. (NIH/NIAMS) [E]	Required Attendee	Accepted
Koroshetz, Walter (NIH/NINDS) [E]	Required Attendee	Accepted
Lea, Allison (NIH/OD) [C]	Required Attendee	Accepted
Lifton, Richard	Required Attendee	None
Lundberg, Jan	Required Attendee	Declined -- unavoidable conflict/had originally accepted
Paltoo, Dina (NIH/OD) [E]	Required Attendee	Accepted
Rodgers, Griffin (NIH/NIDDK) [E]	Required Attendee	Accepted
Ryan, Laurie (NIH/NIA) [E]	Required Attendee	Accepted
Serrate-Sztein, Susana (NIH/NIAMS) [E]	Required Attendee	None
Smith, Philip (NIH/NIDDK) [E]	Required Attendee	Accepted
Spear, Nicole (FNIH) [T]	Required Attendee	Accepted
Sutherland, Margaret (NIH/NINDS) [E]	Required Attendee	Accepted
Terry, Sharon MA	Required Attendee	Accepted
Whitaker, Sanya (FNIH) [T]	Required Attendee	Accepted
Wholley, David (FNIH) [T]	Required Attendee	Accepted

From: Wholley, David (FNIH) [T]
Sent: Wed, 26 Oct 2016 13:41:08 -0400
To: Collins, Francis (NIH/OD) [E]
Subject: RE: AMP EC Pre-Call

Sure I'm on another call but will jump off.

From: Collins, Francis (NIH/OD) [E]
Sent: Wednesday, October 26, 2016 1:41 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: RE: AMP EC Pre-Call

Can we discuss please (b) (6)

From: Wholley, David (FNIH) [T]
Sent: Wednesday, October 26, 2016 1:25 PM
To: Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Collins, Francis (NIH/OD) [E] (b) (6)>; Gadbois, Ellen (NIH/OD) [E] (b) (6); Lea, Allison (NIH/OD) [C] (b) (6); NIHDirectorMeetings <NIHDirectorMeetings@mail.nih.gov>; Hudson, Kathy (NIH/OD) [E] (b) (6) Wood, Gretchen (NIH/OD) [E] (b) (6) Doswell, Greta (NIH/OD) [E] (b) (6) Boskent, Celeste (NIH/OD) [E] (b) (6); Di Mantova, Emma (NIH/OD) [E] (b) (6) McManus, Ayanna (NIH/OD) [E] (b) (6); Hoffmann, Steve (FNIH) [T] <shoffmann@fnih.org>; Spear, Nicole (FNIH) [T] <nspear@fnih.org>; Whitaker, Sanya (FNIH) [T] <swhitaker@fnih.org>; Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnih.org>; Morgan, Emily (FNIH) [T] <emorgan@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: RE: AMP EC Pre-Call
Importance: High

<< File: AMP EC Slides October 28, 2016 DRAFT.pptx >> << File: 2016-09-23_AMP_EC_Telecon_minutes_RLA.docx >> << File: Copy of AMP - EC Attendance for Oct28.xlsx >>

I am assuming we are going forward with our meeting Friday morning and with our pre-call at 2PM. Here are the materials. Sorry for the late note.

David

-----Original Appointment-----
From: Melencio, Cheryl (FNIH) [T]
Sent: Wednesday, October 12, 2016 4:47 PM
To: Melencio, Cheryl (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Lea, Allison (NIH/OD) [C]; NIHDirectorMeetings; Hudson, Kathy (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Doswell, Greta (NIH/OD) [E]; Boskent, Celeste (NIH/OD) [E]; Di Mantova, Emma (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Wholley, David (FNIH) [T]; Hoffmann, Steve (FNIH) [T]; Spear, Nicole (FNIH) [T]; Whitaker, Sanya (FNIH) [T]; Canet-Aviles, Rosa (FNIH) [T]; Morgan, Emily (FNIH) [T]; Menetski, Joseph (FNIH) [T]
Subject: AMP EC Pre-Call
When: Wednesday, October 26, 2016 2:00 PM-2:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: (b) (6) Participant code: (b) (6) Moderator code: (b) (6) Project code: (b) (6)

From: Wholley, David (FNIH) [T]
Sent: Sun, 13 Nov 2016 21:28:31 -0500
To: Collins, Francis (NIH/OD) [E]
Subject: RE: Hever Group...Update

FYI I have drafted something and am just having my team take a look at it. Should have something to you eod tomorrow. David

---

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, November 10, 2016 2:38 PM
To: Green, Eric (NIH/NHGRI) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: FW: Hever Group...Update

Hi Eric and David,

See query below from Trevor Jones of the Hever Group.

Eric, can you provide any update on item 1? There was some discussion about inviting pharma reps to a discussion of how ClinGen was evolving. Did anything come of that?

David, can you get staff to provide bullets to answer the AMP and PACT questions?

I'll deal with the rest.

FC

From: Prof Trevor M Jones CBE [mailto:trevor.m.jones@btinternet.com]
Sent: Thursday, November 10, 2016 10:24 AM
To: Collins, Francis (NIH/OD) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6)
Subject: Hever Group...Update

Francis

You will remember that at our Hever meeting in April in NYC we discussed the "Diagnostics Initiative" and you updated the meeting on several key NIH projects

I am planning to send an update to those attending the Meeting and wonder whether you could let me have one or two "bullets " on each of the Action points listed below ?

My summary slides were as follows

---

1. **Diagnnostics Initiative**

- Principal objective is to move from single Dx profiling to approved Multiplex assays as a prelude to full
  DNA sequencing, proteomic ,transcriptomics.
- NIH ClinGen database curates literature and seeks to identify valid profiles
  ...Needs input from Hever initiative
- Plus continuing the discussion on the regulatory complexities
  e.g. peri/post-LOE drugs

ACTION NIH to examine possibility of hosting a meeting to review current projects / progress.

If so… poll interest of Hever members to participate .

FrC

---

2. NIH Update

- **AMP 3 projects**
  - Alzheimer's disease
  – Autoimmune disorders (rheumatoid arthritis and systemic lupus erythematosus)
  – Type 2 diabetes

  Possible New project proposals ……Parkinson's Disease
  ? Antibiotic Resistance Medicines and vaccines, schizophrenia ,others

FrC

- **National Cancer Moonshot**
  Industry (and Academia etc) being consulted re establishment of and priorities
  for Partnership for accelerating cancer therapies PACT

FrC

- **Precision Medicine Cohort (PMI Cohort)**
  Target is to enrol 1m (could be more !) by 2019
  Good links to UK Biobank
  34 longitudinal genomics data bases globally (with >100,000 subjects)
  …need to determine who might curate /combine the data

FrC

Best personal regards
Trevor

Prof Trevor M Jones CBE FMedSci

From: Wholley, David (FNIH) [T]
Sent: Thu, 27 Oct 2016 08:07:27 -0400
To: Collins, Francis (NIH/OD) [E]
Subject: Re: mail for AMP EC cancellation

Will do.
Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, October 27, 2016 6:23 AM
To: Wholley, David (FNIH) [T]
Cc: Melencio, Cheryl (FNIH) [T]; Wood, Gretchen (NIH/OD) [E]; Boskent, Celeste (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Di Mantova, Emma (NIH/OD) [E]
Subject: RE: mail for AMP EC cancellation

Probably best to send a separate note to Jan and Francis to inquire whether their general problems with Friday 8 AM would get in the way of December 16, or whether they could act now to protect that time.

FC

From: Wholley, David (FNIH) [T]
Sent: Wednesday, October 26, 2016 3:55 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Wood, Gretchen (NIH/OD) [E] (b) (6)>; Boskent, Celeste (NIH/OD) [E] (b) (6); McManus, Ayanna (NIH/OD) [E] (b) (6); Di Mantova, Emma (NIH/OD) [E] (b) (6)
Subject: mail for AMP EC cancellation

Francis—
Sorry to bother you but before I send out the cancellation note below I wanted to ask about the December Extended EC call, which is currently scheduled for 8-9:30 AM EST on Friday, December 16. Knowing what we now know, it is likely Francis and Jan would have to miss the first hour of the call. If we try to move it to 7AM, they'd miss the last half hour (which might be worse). How would you like to play this one? As a reminder we sought the early hour for this in particular to accommodate our European-based colleagues. Thanks, David

Dear AMP EC members and SC co-chairs:

It appears some of our AMP Executive Committee members now have standing conflicts that prevent them from making our standard 8AM time slot on Fridays once a month. **Since it appears we will be missing some key participants for this week's meeting we have decided to cancel this Friday's AMP Executive Committee call, scheduled for 8:00 AM EDT.** We will send around a summary of where we stand on AMP in its stead, and reconvene the EC in November.

In the longer term we are proposing changing the timing and frequency of the calls. It has been proposed that we change the time of the next scheduled call on Friday, November 18 from 8:AM to 7:00

AM EDT, and then reduce the frequency of the EC calls to once every two months thereafter (i.e., 7AM on the last Friday of January, March, May, and so forth).

Is this possible? Can you please respond with your revised availability to Cheryl Melencio (cmelencio@fnih.org)? Thank you for your understanding and commitment.

Regards,
David Wholley

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
9650 Rockville Pike | Bethesda, MD 20814 | **fnih.org**
Direct (301) 594-6343 | dwholley@fnih.org



For 13 consecutive years, Charity Navigator has rated the FNIH as an organization that *exceeds industry standards.*

From: Wholley, David (FNIH) [T]
Sent: Fri, 7 Oct 2016 16:39:59 -0400
To: Chin, Bill;Collins, Francis (NIH/OD) [E]
Cc: Koch-Temp, Kellie
Subject: RE: PACT, AMP, PM Discussion at PhRMA

Bill, we have our FNIH Board Meeting up in Bethesda that day, but if you can move the time to 2PM I should be able to make it.
David

From: Chin, Bill [mailto:Chin@phrma.org]
Sent: Friday, October 07, 2016 1:07 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Koch-Temp, Kellie <KKoch@phrma.org>
Subject: RE: PACT, AMP, PM Discussion at PhRMA

Thanks, Francis. I appreciate the quick reply. David—Perhaps you could join us? Would you be willing?
Bill

From: Collins, Francis (NIH/OD) [E] (b) (6)
Sent: Thursday, October 06, 2016 9:32 PM
To: Chin, Bill
Cc: Wholley, David (FNIH) [T]; Koch-Temp, Kellie
Subject: RE: PACT, AMP, PM Discussion at PhRMA

HI Bill,

This does indeed sound like a great opportunity, but I regret I won't be able to take part – I will be accompanying Secretary Burwell on an official foreign visit that day.

Best regards, Francis

From: Chin, Bill [mailto:Chin@phrma.org]
Sent: Thursday, October 06, 2016 3:33 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Koch-Temp, Kellie <KKoch@phrma.org>
Subject: PACT, AMP, PM Discussion at PhRMA

Hi Francis (and David), I trust all is well. On Thursday, October 20, 2016, I have convened the PhRMA Biomedical Advisory Council (BMAC) for a biannual meeting at PhRMA in DC. You may recall that BMAC members include our member company CSOs, CMOs and CDOs such Cuss, Dolsten, Permutter and Zerhouni. One of the topics to be covered is Public-Private Partnerships which includes PACT, AMP and Precision Medicine. I know that this ridiculously short notice but I wonder whether this might be an opportunity to talk to our science and medicine leaders about the progress and promise of NIH-industry interactions such as these. The session is scheduled in the 1:30—2:30 PM time-frame. It would be great if you could lead this discussion. Let me know if you have any questions. Bill

From: Wholley, David (FNIH) [T]
Sent: Fri, 7 Oct 2016 17:35:37 -0400
To: Chin, Bill;Collins, Francis (NIH/OD) [E]
Cc: Koch-Temp, Kellie
Subject: RE: PACT, AMP, PM Discussion at PhRMA

Please let me know what you'd like to cover, format, time for discussion, what you think they want to hear, etc. I am thinking keep this high level, minimal number of slides

---

From: Chin, Bill [mailto:Chin@phrma.org]
Sent: Friday, October 07, 2016 4:48 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Koch-Temp, Kellie <KKoch@phrma.org>
Subject: RE: PACT, AMP, PM Discussion at PhRMA

David, I can move the time to 2—2:30 PM on Thursday, 10/27. If we can help with transportation, just let us know. This is fantastic! Thanks. And have a great weekend. Bill

---

From: Wholley, David (FNIH) [T] [mailto:dwholley@fnih.org]
Sent: Friday, October 07, 2016 4:40 PM
To: Chin, Bill; Collins, Francis (NIH/OD) [E]
Cc: Koch-Temp, Kellie
Subject: RE: PACT, AMP, PM Discussion at PhRMA

Bill, we have our FNIH Board Meeting up in Bethesda that day, but if you can move the time to 2PM I should be able to make it.
David

From: Chin, Bill [mailto:Chin@phrma.org]
Sent: Friday, October 07, 2016 1:07 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Koch-Temp, Kellie <KKoch@phrma.org>
Subject: RE: PACT, AMP, PM Discussion at PhRMA

Thanks, Francis. I appreciate the quick reply. David—Perhaps you could join us? Would you be willing?
Bill

From: Collins, Francis (NIH/OD) [E] (b) (6)]
Sent: Thursday, October 06, 2016 9:32 PM
To: Chin, Bill
Cc: Wholley, David (FNIH) [T]; Koch-Temp, Kellie
Subject: RE: PACT, AMP, PM Discussion at PhRMA

HI Bill,

This does indeed sound like a great opportunity, but I regret I won't be able to take part – I will be accompanying Secretary Burwell on an official foreign visit that day.

Best regards, Francis

From: Chin, Bill [mailto:Chin@phrma.org]
Sent: Thursday, October 06, 2016 3:33 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Koch-Temp, Kellie <KKoch@phrma.org>
Subject: PACT, AMP, PM Discussion at PhRMA

Hi Francis (and David), I trust all is well. On Thursday, October 20, 2016, I have convened the PhRMA Biomedical Advisory Council (BMAC) for a biannual meeting at PhRMA in DC. You may recall that BMAC members include our member company CSOs, CMOs and CDOs such Cuss, Dolsten, Permutter and Zerhouni. One of the topics to be covered is Public-Private Partnerships which includes PACT, AMP and Precision Medicine. I know that this ridiculously short notice but I wonder whether this might be an opportunity to talk to our science and medicine leaders about the progress and promise of NIH-industry interactions such as these. The session is scheduled in the 1:30—2:30 PM time-frame. It would be great if you could lead this discussion. Let me know if you have any questions. Bill

From: Wholley, David (FNIH) [T]
Sent: Mon, 8 Aug 2016 13:51:06 -0400
To: Collins, Francis (NIH/OD) [E];Lowy, Douglas (NIH/NCI) [E];Doroshow, James (NIH/NCI) [E];Adam, Stacey (FNIH) [T];Rosema, Laura (NIH/OD) [E];Baker, Rebecca (NIH/OD) [E]
Subject: Re: PACT update and working group process

Thanks Francis. We will follow up with Jeff immediately.
Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Monday, August 8, 2016 1:22 PM
To: Wholley, David (FNIH) [T]; Lowy, Douglas (NIH/NCI) [E]; Doroshow, James (NIH/NCI) [E]; Adam, Stacey (FNIH) [T]; Rosema, Laura (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]
Subject: FW: PACT update and working group process

From: Bradner, James [mailto:james.bradner@novartis.com]
Sent: Monday, August 08, 2016 12:02 PM
To: Collins, Francis (NIH/OD) [E]
Subject: Re: PACT update and working group process

francis, thank you for the note and hello from sunny nantucket. jeff would be perfectly suited to this role - please do reach out! jay

Jay Bradner, M.D.
President | Novartis Institutes for BioMedical Research
james.bradner[at]novartis.com

From: "Collins, Francis (NIH/OD) [E]" (b) (6)>
Date: Monday, August 8, 2016 at 11:56 AM
To: "Bradner, James" <james.bradner@novartis.com>
Cc: "Hudson, Kathy (NIH/OD) [E]" (b) (6), "Lowy, Douglas (NIH/NCI) [E]" (b) (6) James Doroshow (b) (6)>, "Wholley, David (FNIH) [T]" <dwholley@fnih.org>, "Adam, Stacey (FNIH) [T]" <sadam@fnih.org>, "Rosema, Laura (NIH/OD) [E]" (b) (6)>, "Baker, Rebecca (NIH/OD) [E]" (b) (6)
Subject: RE: PACT update and working group process

Hey there Jay,

We're hoping to get this working group underway quickly – is it OK for us to ask Jeff Engelman to help? See below.

Thanks, Francis

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, July 28, 2016 11:11 PM
To: 'James.bradner@novartis.com'
Cc: Hudson, Kathy (NIH/OD) [E]; Lowy, Douglas (NIH/NCI) [E]; Doroshow, James (NIH/NCI) [E]; Wholley, David (FNIH) [T]; Adam, Stacey (FNIH) [T]; Rosema, Laura (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]
Subject: PACT update and working group process

Dear Jay,

Thanks again for your words of support and enthusiasm for our partnership efforts at the New Democrats luncheon. I wanted to update you on some significant progress we've made on the Partnership for Accelerating Cancer Therapies (PACT), and to ask if Jeff Engelman could play a key leadership role in the effort.

The Vice-President cited PACT from the podium at the White House Cancer Moonshot Summit on June 29th as one of the more exciting opportunities in the Moonshot. After extensive conversations with potential partners and stakeholders, we've selected two focus areas for PACT:

1. **Identification and validation of biomarkers for the response to cancer therapies**
2. **Establishment of a platform for combination clinical trials**

We believe these areas will address the most pressing current needs in the immuno-oncology field, and are uniquely suited for a pre-competitive research collaboration.

Given the excitement and momentum generated by the Moonshot, we're eager to move PACT into the next phase of development, which involves convening a "Working Group" of experts from NCI, industry, patient groups, and academia to agree on a suitable research plan. From our experience with AMP, we intend to select one industry scientist and one NCI representative to co-chair the Working Group. Both Doug Lowy and Jim Doroshow of NCI enthusiastically recommended Jeff to serve as the industry co-chair for focus area #2 in combination clinical trials.

The time commitment for Jeff would entail 3 teleconferences (a couple of hours each) and at least one in-person 2-day meeting in the early fall, with the key deliverable a white paper describing the consensus of the group on a common mission and a high level plan. Others from the Novartis Oncology group could also aid in the development of a detailed plan once the white paper is completed. Given

how fast the field is moving, we'd like to solidify a plan and gather the necessary funding commitments by the end of this year, with a view to launching an effort in early 2017. We are engaging the Foundation for the NIH to manage this effort, and Jeff would be fully staffed by FNIH to make this successful.

Would you be willing to consider Jeff in this role? I will be out of the country next week, but David Wholley at FNIH (copied) can answer any detailed questions about the process, and I am happy to speak when I return on August 9th.

Best personal regards,

Francis

From: Wholley, David (FNIH) [T]
Sent: Thu, 1 Sep 2016 16:26:26 -0400
To: Collins, Francis (NIH/OD) [E]
Subject: RE: PACT Working Group Member Calls - (b) (5)

(b) (5)

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, September 01, 2016 4:25 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: RE: PACT Working Group Member Calls - (b) (5)

(b) (5)

From: Wholley, David (FNIH) [T]
Sent: Thursday, September 01, 2016 3:37 PM
To: Collins, Francis (NIH/OD) [E]
Subject: PACT Working Group Member Calls - (b) (5)

Hi Francis:

Things are going quite well with the first focus group in PACT (biomarkers), co-chaired by Alex Hoos of GSK and Helen Chen at NCI. We have had several calls with the co-chairs and have begun drafting up an outline of a white paper to feed into a planned face to face on September 22. For Focus Group 2 (combination therapy trials), which is co-chaired by Jeff Engelman of Novartis and Percy Ivy of NCI, however, while we have had very good input from Percy and have had Jeff on one introductory telecon, we are tearing our hair out trying to get any sort of availability from Jeff for further teleconferences, much less the face to face. I have written to him myself but he appears to be out (on vacation perhaps) until Tuesday 9/6, and his assistant has not been able to be of much help. (We also now have, by the way, positive responses on contributions to and participation in the PACT design effort from seven companies, (b) (4)

I am conscious that Jeff is involved because of your relationship with and request to Jay Bradner. But this is already a threat to schedule and I think it is time to either establish Jeff's ability to commit the necessary time to this effort, or regretfully seek another co-chair. How would you like to proceed?

Thanks, David

From: Caulfield, Anita [mailto:anita.caulfield@novartis.com]
Sent: Thursday, September 01, 2016 11:58 AM
To: Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Subject: Re: PACT Working Group Member Orientation Call - (b) (5)

Hi Stacy,

No worries. Jeff is not available on those dates, sorry. I can tell you that Jeff's next 2-hour opening is in the first week of October.

Thanks,
Anita

On Sep 1, 2016, at 11:45 AM, Adam, Stacey (FNIH) [T] <sadam@fnih.org> wrote:

Hi Anita,

I know you are likely tired of hearing from me. Could you please tell me if Jeff would be available for a 2 hour call at either of the following two times next week?

September 6th – 4-6pm

September 7th – 4-6pm

Thanks,
Stacey

Stacey J. Adam, Ph.D.
Scientific Program Manager, Cancer
Foundation for the National Institutes of Health
Direct (301) 435-8364 | Mobile [redacted] (b) (6)

From: Adam, Stacey (FNIH) [T]
Sent: Wednesday, August 31, 2016 1:40 PM
To: Caulfield, Anita <anita.caulfield@novartis.com>
Subject: Re: PACT Working Group Member Orientation Call - [redacted] (b) (5)

Hi Anita,

I am sorry to be a pain, but two questions.

Would you have time to fill out the Doodle poll for Jeff's availability today? Or send me his availability for a 2 hour call next week between Sep 6-9 via email? We are desperate to lock down a time for our first Working Group call, but we need Jeff's schedule to do so.

Also, my director wanted me to ask if there was a possibility of moving Jeff's meeting on Sep 22. This is a very important initiative for the White House Cancer Moonshot and we are on very tight timelines from the WH to get this finished and really need to have this first meeting in late September. Most members can do the 22, but we really need all of our chairs there. If this is possible, I am happy to discuss the need of the phone with you.

Thanks,
Stacey

Sent from my BlackBerry 10 smartphone.

From: Adam, Stacey (FNIH) [T]
Sent: Tuesday, August 30, 2016 4:18 PM
To: Caulfield, Anita
Subject: RE: PACT Working Group Member Orientation Call - (b) (5)

Thanks, Anita,

This was expected, but I wanted him to know they were taking place.

Also, have you had a chance to fill out the fixed Doodle poll link I sent yesterday? Or any thoughts on the availability document?

I know this is a lot, but any help you can provide would be most helpful.

Thanks,
Stacey

Stacey J. Adam, Ph.D.
Scientific Program Manager, Cancer
Foundation for the National Institutes of Health
Direct (301) 435-8364 | Mobile (b) (6)

-----Original Appointment-----
From: Caulfield, Anita [mailto:anita.caulfield@novartis.com] **On Behalf Of** Engelman, Jeffrey
Sent: Tuesday, August 30, 2016 4:13 PM
To: Adam, Stacey (FNIH) [T]
Subject: Tentative: PACT Working Group Member Orientation Call - (b) (5)
When: Thursday, September 01, 2016 2:30 PM-3:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Conference Line: (b) (6) Participant Code: (b) (6) Moderator code: (b) (6) Project code (b) (6)

Jeff is currently out of the office traveling and will not be able to participate in this call on 9/1.

From: Wholley, David (FNIH) [T]
Sent: Sun, 21 Aug 2016 13:48:21 -0400
To: Pazdur, Richard (FDA/CDER);Robert Califf;Woodcock, Janet (FDA/CDER);Collins, Francis (NIH/OD) [E];Sherman, Rachel (FDA/OC);Kraus, Tom (FDA/OC);Zimmer, Natale (FDA/OC);Kim, Geoffrey (FDA/CDER);Kim, Tamy (FDA/CDER);McKee, Amy (FDA/CDER);Kluetz, Paul (FDA/CDER);Theoret, Marc (FDA/CDER);Blumenthal, Gideon (FDA/CDER);Mansfield, Elizabeth (FDA/CDRH)
Cc: Rosema, Laura (NIH/OD) [E];Lowy, Douglas (NIH/NCI) [E];Hudson, Kathy (NIH/OD) [E];Doroshow, James (NIH/NCI) [E];Baker, Rebecca (NIH/OD) [E];Adam, Stacey (FNIH) [T]
Subject: RE: Partnership for Accelerating Cancer Therapies (PACT)

Great, Rick. Stacey Adam from our staff will be in touch to let you know where we are and next steps.
David

From: Pazdur, Richard (FDA/CDER)
Sent: Saturday, August 20, 2016 10:48 AM
To: Robert Califf (b) (6); Woodcock, Janet (FDA/CDER) (b) (6) Collins, Francis (NIH/OD) [E] (b) (6); Sherman, Rachel (FDA/OC) (b) (6) Kraus, Tom (FDA/OC) (b) (6); Zimmer, Natale (FDA/OC) (b) (6); Kim, Geoffrey (FDA/CDER) (b) (6) Kim, Tamy (FDA/CDER) (b) (6) McKee, Amy (FDA/CDER) (b) (6) Kluetz, Paul (FDA/CDER) (b) (6) Theoret, Marc (FDA/CDER) (b) (6)>; Blumenthal, Gideon (FDA/CDER) (b) (6) Mansfield, Elizabeth (FDA/CDRH) (b) (6)>
Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Rosema, Laura (NIH/OD) [E] (b) (6) Lowy, Douglas (NIH/NCI) [E] (b) (6); Hudson, Kathy (NIH/OD) [E] (b) (6); Doroshow, James (NIH/NCI) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6)>; Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Subject: RE: Partnership for Accelerating Cancer Therapies (PACT)

Be happy to participate. Please loop me in on the future plans.

From: Califf, Robert
Sent: Saturday, August 20, 2016 8:25 AM
To: Woodcock, Janet; Collins, Francis S (NIH); Pazdur, Richard; Sherman, Rachel; Kraus, Tom; Zimmer, Natale
Cc: Wholley, David N (NIH); Rosema, Laura S (NIH); Lowy, Douglas R (NIH); Hudson, Kathy L (NIH); Doroshow, Jim H (NIH); Baker, Rebecca G (NIH); Adam, Stacey J (NIH)
Subject: RE: Partnership for Accelerating Cancer Therapies (PACT)

Francis,

This is something Janet and Rick Pazdur should take on. I will follow with great interest. Congrats on getting to this point.

rmc

Robert M Califf MD
Commissioner of Food and Drugs

From: Woodcock, Janet
Sent: Sunday, August 14, 2016 8:37 AM
To: Collins, Francis S (NIH); Califf, Robert
Cc: Wholley, David N (NIH); Rosema, Laura S (NIH); Lowy, Douglas R (NIH); Hudson, Kathy L (NIH); Doroshow, Jim H (NIH); Baker, Rebecca G (NIH); Adam, Stacey J (NIH)
Subject: Re: Partnership for Accelerating Cancer Therapies (PACT)

These are both of great interest to both FDA oncology and me personally. Rick is out of the country right now but at least from CDER we are very eager to participate. We are very aware of the need for bio markers (just had a scientist from Australia propose a new candidate for the checkpoint inhibitors) but a lot of work needs to be done. A clinical platform could help with that effort as well. I'll await Rib'sdirection on how he wants our participation arranged. Jw

---

From: Collins, Francis (NIH/OD) [E] (b) (6)
Date: August 13, 2016 at 10:14:52 PM EDT
To: Califf, Robert (b) (6), Woodcock, Janet (b) (6)
Cc: Adam, Stacey J (NIH) <sadam@fnih.org>, Rosema, Laura S (NIH) (b) (6)
Wholley, David N (NIH) <dwholley@fnih.org>, Baker, Rebecca G (NIH) (b) (6)
Doroshow, Jim H (NIH) (b) (6), Hudson, Kathy L (NIH)
(b) (6), Lowy, Douglas R (NIH) (b) (6)>
Subject: Partnership for Accelerating Cancer Therapies (PACT)

Hi Rob and Janet,

I am writing to ask your help in ways to involve FDA formally in the nascent Partnership for Accelerating Cancer Therapies (PACT). We have been discussing this public-private partnership with the White House and with industry and cancer non-profits over the last few months, and it is now beginning to take shape. Since the initial calls about the partnership (in which I know you participated) and the Cancer Moonshot Summit (at which the Vice-President mentioned PACT) we have had further discussions with NCI leadership and some industry oncology leads that have winnowed the original four focus areas we'd been discussing down to two:

1. **Identification and validation of biomarkers for response and resistance to cancer immunotherapies**
2. **Establishment of a platform for selecting and testing combination therapies**

(Support for the other two areas, disease modeling and rare cancers, was confined to relatively fewer partners and could be, we felt, addressed as part of our focus on the first two areas).

I have also meanwhile asked the Foundation for the NIH to take over the effort to design specific research agendas for the two lead focus areas, using a process similar to what we used to develop the Accelerating Medicines Partnership (AMP). FNIH has begun to establish two workgroups--with pharma, NIH and academic researchers represented in each--to develop a "white paper" level description of

potential research agenda as a tool for confirming funding and participation. Since both of the PACT focus areas have strong regulatory science implications and are obviously relevant to FDA's mission, I would be grateful if you would consider nominating at least one scientist from FDA to serve on each of these workgroups. My understanding is that the initial time commitment for this would consist of 3-4 teleconferences (~2 hours each) and 2 in-person meetings (~1.5 days each) beginning in late August and concluding just before Thanksgiving in November. The idea is to have initial consensus around research agendas and willingness of specific partners to fund by December, with a PACT launch in spring or summer of 2017.

Please let me know your thoughts, and don't hesitate to reach out either to me or to David Wholley at FNIH with any questions.

(b) (6)

Francis

From: Wholley, David (FNIH) [T]
Sent: Thu, 3 Nov 2016 14:59:25 -0400
To: Collins, Francis (NIH/OD) [E]
Subject: Re: Peter Stein / Caroline Fox

Thanks for the heads up, Francis. Does Phil know about this? (b) (5)

(b) (5)

David
Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, November 3, 2016 2:42 PM
To: Wholley, David (FNIH) [T]; Smith, Philip (NIH/NIDDK) [E]; Rodgers, Griffin (NIH/NIDDK) [E]
Cc: Gadbois, Ellen (NIH/OD) [E]
Subject: FW: Peter Stein / Caroline Fox

(b) (5)

From: Miletich, Joseph [mailto:joseph.miletich@merck.com]
Sent: Thursday, November 03, 2016 11:56 AM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Subject: Peter Stein / Caroline Fox

Hi Francis,

I hope you are well.

(b) (5)

Please let me know if you need anything other than this email to effect this change, or if you would like to discuss it .
With best regards.

Joe

Notice: This e-mail message, together with any attachments, contains information of Merck & Co., Inc. (2000 Galloping Hill Road, Kenilworth, New Jersey, USA 07033), and/or its affiliates Direct contact information for affiliates is available at http://www.merck.com/contact/contacts.html) that may be confidential, proprietary copyrighted and/or legally privileged. It is intended solely for the use of the individual or entity named on this message. If you are not the intended recipient, and have received this message in error,

please notify us immediately by reply e-mail and then delete it from your system.

From: Wholley, David (FNIH) [T]
Sent: Thu, 3 Nov 2016 15:56:28 -0400
To: Rodgers, Griffin (NIH/NIDDK) [E];Collins, Francis (NIH/OD) [E]
Subject: RE: Peter Stein / Caroline Fox

Thanks, Griff, (b) (5)
(b) (5)

From: Rodgers, Griffin (NIH/NIDDK) [E]
Sent: Thursday, November 03, 2016 3:52 PM
To: Collins, Francis (NIH/OD) [E] (b) (6) Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: Re: Peter Stein / Caroline Fox

Hi Francis:

(b) (5)

Best,

Griff

From: "Collins, Francis (NIH/OD) [E]" (b) (6)>
Date: Thursday, November 3, 2016 at 2:42 PM
To: "Wholley, David (FNIH) [T]" <dwholley@fnih.org>, "Smith, Philip (NIH/NIDDK) [E]" (b) (6), "Rodgers, Griffin (NIH/NIDDK) [E]" (b) (6)
Cc: "Gadbois, Ellen (NIH/OD) [E]" (b) (6)
Subject: FW: Peter Stein / Caroline Fox

(b) (5)

From: Miletich, Joseph [mailto:joseph.miletich@merck.com]
Sent: Thursday, November 03, 2016 11:56 AM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Subject: Peter Stein / Caroline Fox

Hi Francis,

I hope you are well.

(b) (5)

Please let me know if you need anything other than this email to effect this change, or if you would like to discuss it .
With best regards.

Joe

Notice: This e-mail message, together with any attachments, contains information of Merck & Co., Inc. (2000 Galloping Hill Road, Kenilworth, New Jersey, USA 07033), and/or its affiliates Direct contact information for affiliates is available at http://www.merck.com/contact/contacts.html) that may be confidential, proprietary copyrighted and/or legally privileged. It is intended solely for the use of the individual or entity named on this message. If you are not the intended recipient, and have received this message in error, please notify us immediately by reply e-mail and then delete it from your system.

From: Wholley, David (FNIH) [T]
Sent: Sat, 27 Aug 2016 14:29:42 -0400
To: Collins, Francis (NIH/OD) [E]
Subject: Re: Progress on funding PACT design phase

Just heard from Genentech, so we are now at five.
Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Saturday, August 27, 2016 11:56 AM
To: Wholley, David (FNIH) [T]
Cc: Adam, Stacey (FNIH) [T]; Baker, Rebecca (NIH/OD) [E]; Rosema, Laura (NIH/OD) [E]; Wolf-Rodda, Julie (FNIH) [T]; Donnelly, Meredith (FNIH) [T]
Subject: Re: Progress on funding PACT design phase

Excellent!

Sent from my iPhone

On Aug 26, 2016, at 4:06 PM, Wholley, David (FNIH) [T] <dwholley@fnih.org> wrote:

Hi Francis:

(b) (4)

David

From: Wholley, David (FNIH) [T]
Sent: Wed, 26 Oct 2016 09:55:46 -0400
To: Collins, Francis (NIH/OD) [E]
Subject: RE: Availability for AMP Executive Committee Telecon -- October 28, 2016
Importance: High

To summarize, here's what we heard:
Cuss: Has CEO meeting at 8 every Friday. Can do 7-8 am or 5-6 PM. Reducing frequency of calls would be helpful. Cannot make this Friday's meeting.
Dolsten: Suggests we make calls every 2-3 months. Can call in this Friday from 8-8:40 if needed, but depends on airport logistics. His office has also suggested Martin Sogaard can attend.
Lundberg: Has CEO meeting at 8 every Friday. Best to do calls after lunch. Suggests regular meetings once a quarter with separate calls for urgent issues in between as needed. Cannot make this Friday's meeting.

My proposals:
7 am is fine and agree we should propose that first.
If not, 5-6 PM would seem to the be the next best proposed time.
We should reduce the frequency to every other month to start, see how it goes.

Given the above, what would you like to do about this Friday's meeting? The agenda is all in the way of updates (PD fundraising is proceeding, AMP RA/SLE revised milestone decision was voted on and accepted, tau scans and network AD analysis proceeding, T2D portal functionality and efforts to attract new data continue to evolve). Pretty much everyone else can make it so far.

Please let me know and we'll make it happen.

Thanks, David

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, October 25, 2016 3:14 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: FW: Availability for AMP Executive Committee Telecon -- October 28, 2016

Seems like we need to change the schedule, as Friday 8 AM is a bad choice for Jan and Francis. Want to propose some options? I'm fine with 7 AM calls.

Francis

From: Cuss, Francis [mailto:francis.cuss@bms.com]
Sent: Tuesday, October 25, 2016 11:24 AM
To: Collins, Francis (NIH/OD) [E] (b) (6); Dolsten, Mikael <Mikael.Dolsten@pfizer.com>; lundberg_jan@lilly.com
Cc: Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Wholley, David (FNIH) [T] <dwholley@fnih.org>; Gadbois, Ellen (NIH/OD) [E] (b) (6); Wood, Gretchen (NIH/OD) [E]

(b) (6); Boskent, Celeste (NIH/OD) [E] (b) (6); Di Mantova, Emma (NIH/OD) [E] (b) (6) McManus, Ayanna (NIH/OD) [E] (b) (6)
Subject: RE: Availability for AMP Executive Committee Telecon -- October 28, 2016

Dear Francis,

Thanks for the note. Unfortunately I too have a meeting arranged by my CEO this Friday. Clearly reducing the frequency of the meetings would be helpful, but unfortunately it's the unexpected that generally ruins my availability.

Personally I find it easier to keep the time at the beginning and the end of the working day free (i.e. 700am-800am and 500-600pm), but appreciate this is not possible for everyone.

However like Jan and Mikael, whatever you decide I remain committed to AMP and will endeavor to free up my time to call in for the meetings you set up.

Best,
Francis

From: Collins, Francis (NIH/OD) [E] (b) (6)
Sent: Monday, October 24, 2016 5:29 PM
To: Dolsten, Mikael <Mikael.Dolsten@pfizer.com>; Cuss, Francis <francis.cuss@bms.com>; lundberg_jan@lilly.com
Cc: Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Wholley, David (FNIH) [T] <dwholley@fnih.org>; Gadbois, Ellen (NIH/OD) [E] (b) (6); Wood, Gretchen (NIH/OD) [E] (b) (6); Boskent, Celeste (NIH/OD) [E] (b) (6) Di Mantova, Emma (NIH/OD) [E] (b) (6); McManus, Ayanna (NIH/OD) [E] (b) (6)
Subject: Availability for AMP Executive Committee Telecon -- October 28, 2016

Dear Mikael, Francis, and Jan:

I have heard from FNIH that none of you will be able to attend our next AMP EC meeting, scheduled for this coming Friday October 28 at 8 AM EDT. I have also noticed that it has been increasingly difficult to align with your schedules for these calls over the last six months or so. I thoroughly enjoy our interactions and consider your input critical to the success of the partnership, but I also appreciate that you are extremely busy and am wondering if there may be a better way to engage you on AMP, particularly given the maturity of the partnership at this point.

Should we keep the concept of a one hour teleconference, but have them less frequently? If so, should we reduce the frequency to every two months? Once a quarter? Or is there another path here you'd suggest we follow?

Please let me know your thoughts on this.

Regards,
Francis

This message (including any attachments) may contain confidential, proprietary, privileged and/or private information. The information is intended to be for the use of the individual or entity designated above. If you are not the intended recipient of this message, please notify the sender immediately, and delete the message and any attachments. Any disclosure, reproduction, distribution or other use of this message or any attachments by an individual or entity other than the intended recipient is prohibited.

From: Wholley, David (FNIH) [T]
Sent: Mon, 3 Oct 2016 12:15:29 -0400
To: Collins, Francis (NIH/OD) [E]
Subject: RE: checking in

Sure, Francis:

PACT: On the co-chair issue, Jeff Engelman's involvement has still really been adequate, but we think we have found a way to work around the issue.

After your email to Jay Bradner, Jeff did make the 2-hour pre-call for the face to face meeting, but was not able to attend the face to face itself. At that meeting however, the group decided to combine the two focus areas into one because of the interaction between the biomarker and combination therapy agendas. We have not discussed this with Jeff yet, but consensus was to make Alex Hoos of GSK and Percy Ivy of NCI the formal leads on the consolidated working group and weave in Jeff's and Helen Chen (NCI)'s views and participation as they can make themselves available.

The face to face meeting overall went pretty well. In addition to recommending the consolidation of the focus areas, we took the 10-11 different projects spread across both focus areas and took them down to 6 (really 5). We've not consolidated numbering yet, so still listed according to focus area they are:

Focus Area 1: A systematic biomarker road map to understand response and resistance to cancer immunotherapies and enable new treatment strategies

- Project 1: Standardization and harmonization of IO biomarker assays
- Project 2: Biomarker standardization/harmonization
- Project 3: Systematic incorporation of biomarkers into clinical trials, creation of core laboratory network for conducting biomarker testing, and establishment of a database repository of biomarker data
- Project 4: Supercomputing for systems biology analyses of complex data (N.B. this one is not really a project, but will consist of just a paragraph in the white paper acknowledging the importance of doing something in synergy with the Moonshot)

Focus Area 2: Establish a platform for selecting and testing combination therapies

- Project 1: Facilitate intercompany collaborations – create common templates for regulatory agreements, data sharing, etc.
- Project 2: Enhance pre-clinical animal models to collect data to assist in selection of combinations
- Project 3: Combination selection Panel – a Steering Committee to adjudicate combinations

Doug Lowy, Jim Doroshow, and Dinah Singer all attended pieces of the meeting. Jim offered to have Stacey Adam and me come over to walk through NCI's planned investments in the space and strategize how PACT projects can be additive/complementary to their initiatives—we have some ideas on this already, but I think it is a good discussion to have. We are going to meet on October 19.

The biggest issue we face right now is getting the next face to face scheduled in November. It is hard to get all the key people lined up but we are working it.

AMP RA/SLE:
So far all of the companies have said they are generally supportive of the compromise plan to delay the go/no go milestone. The only blip so far is that Merck would like to propose a second go/no-go milestone at the end of year 3 (2017) to make sure the biopsies/data remain on track. We (FNIH) have been attempting to dissuade them from even making this proposal, which all of the other companies would have to accept, and have Bob Carter and Marty Hodge involved. A formal written request regarding the compromise which outlines the issues, proposed solution, and timeline is being sent out to each of the funding partners (and the SC). The goal is to talk through all of this and get the solution approved by the SC on October 11.

Hope this helps. Please let me know any other questions.
Thanks , David

From: Collins, Francis (NIH/OD) [E]
Sent: Monday, October 03, 2016 7:38 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: checking in

Hi David,

Just checking in – [redacted] (b) (5)

FC

From: Wholley, David (FNIH) [T]
Sent: Sun, 18 Sep 2016 12:09:50 -0400
To: Collins, Francis (NIH/OD) [E]
Cc: Adam, Stacey (FNIH) [T];Donnelly, Meredith (FNIH) [T]
Subject: RE: current list of companies interested in PACT

Certainly, Francis. They are as follows:

Committed via email (11 companies + 1 non-profit):
Abbvie
Amgen
AstraZeneca
Bayer
Boehringer-Ingelheim
BMS
EMD Serono
GSK
Lilly
Merck
Pfizer
PhRMA
[BMS has actually signed a funding LOA, the others are in progress with several to sign this week]

Has expressed interest, but has not returned emails regarding funding (1 company):
(b) (4)

(b) (4)

Please let me know any other questions.

David

From: Collins, Francis (NIH/OD) [E]
Sent: Sunday, September 18, 2016 9:57 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Subject: current list of companies interested in PACT

(b) (5)

FC

From: Wholley, David (FNIH) [T]
Sent: Mon, 19 Sep 2016 10:19:44 -0400
To: Collins, Francis (NIH/OD) [E]
Cc: Adam, Stacey (FNIH) [T];Donnelly, Meredith (FNIH) [T]
Subject: RE: current list of companies interested in PACT

Sorry, Francis. Yes, [redacted] (b) (4)

From: Collins, Francis (NIH/OD) [E]
Sent: Sunday, September 18, 2016 2:39 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Adam, Stacey (FNIH) [T] <sadam@fnih.org>; Donnelly, Meredith (FNIH) [T] <mdonnelly@fnih.org>
Subject: Re: current list of companies interested in PACT

[redacted] (b) (4)

Sent from my iPhone

On Sep 18, 2016, at 12:09 PM, Wholley, David (FNIH) [T] <dwholley@fnih.org> wrote:

Certainly, Francis. They are as follows:

Committed via email (11 companies + 1 non-profit):
Abbvie
Amgen
AstraZeneca
Bayer
Boehringer-Ingelheim
BMS
EMD Serono
GSK
Lilly
Merck
Pfizer
PhRMA
[BMS has actually signed a funding LOA, the others are in progress with several to sign this week]

Has expressed interest, but has not returned emails regarding funding (1 company):
[redacted] (b) (4)

[redacted] (b) (4)

(b) (4)

Please let me know any other questions.

David

From: Collins, Francis (NIH/OD) [E]
Sent: Sunday, September 18, 2016 9:57 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Subject: current list of companies interested in PACT

Can you give me an update on companies that have expressed interest in PACT? (b) (5)

FC

From: Wholley, David (FNIH) [T]
Sent: Tue, 11 Oct 2016 22:36:50 -0400
To: Collins, Francis (NIH/OD) [E]
Cc: Smith, Philip (NIH/NIDDK) [E];Whitaker, Sanya (FNIH) [T];Spear, Nicole (FNIH) [T]
Subject: Re: Departure

But we hear his new job is in "government.". Hope it's close to you/us.
Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, October 11, 2016 6:04 PM
To: Wholley, David (FNIH) [T]
Cc: Smith, Philip (NIH/NIDDK) [E]; Whitaker, Sanya (FNIH) [T]; Spear, Nicole (FNIH) [T]
Subject: RE: Departure

Truly sorry that Peter is leaving, he's been great to work with on AMP.

From: Wholley, David (FNIH) [T]
Sent: Tuesday, October 11, 2016 4:50 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)>
Cc: Smith, Philip (NIH/NIDDK) [E] (b) (6)>; Whitaker, Sanya (FNIH) [T] <swhitaker@fnih.org>; Spear, Nicole (FNIH) [T] <nspear@fnih.org>
Subject: FW: Departure

Francis,
Please see below. (b) (5)
David

From: Whitaker, Sanya (FNIH) [T]
Sent: Tuesday, October 11, 2016 3:25 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: FW: Departure

fyi

From: Whitaker, Sanya (FNIH) [T]
Sent: Tuesday, October 11, 2016 3:24 PM
To: 'Stein, Peter Paris' <peter.stein@merck.com>; Spear, Nicole (FNIH) [T] <nspear@fnih.org>
Subject: RE: Departure

Hi Peter,

We very much appreciate your time with us as co-chair and it has been great to be able to work with you. The Steering Committee has made tremendous progress under your and Phil's leadership. Hopefully, we will have the opportunity to work with you again sometime in the future.

Best of luck in your new endeavors.

Kind Regards,

Sanya and Nicole

Sanya Fanous Whitaker, PhD, PMP
Scientific Program Manager – Metabolic Disorders
Division of Research Partnerships
Foundation for the National Institutes of Health

9650 Rockville Pike | Bethesda, MD 20814 | www.fnih.org
Direct (301) 496-1518 | Mobile (b) (6) | swhitaker@fnih.org



For eleven consecutive years, Charity Navigator has rated the FNIH as an organization that exceeds industry standards.

From: Stein, Peter Paris [mailto:peter.stein@merck.com]
Sent: Tuesday, October 11, 2016 3:17 PM
To: Whitaker, Sanya (FNIH) [T] <swhitaker@fnih.org>; Spear, Nicole (FNIH) [T] <nspear@fnih.org>
Subject: Departure

Hi Sanya, Nicole,

As I indicated to you recently, I am leaving Merck – and my role on the SC for AMP/T2DM. It has truly been a pleasure working on this project – and learning from the SC members and you both.

This is my last week at Merck – and I likely will not be able to call in on Friday.

I have asked Roger Perlmutter to assign a replacement, which, as yet, he has not done. Hopefully, another SC representative from Merck will be assigned in the near future – of course, Dermot will remain a key SC member in support of this important effort.

Again, thanks – and please express my appreciation to the entire SC for their efforts and collaboration over the past year…

Warm Regards, Peter

Peter P. Stein, MD
Vice-president, Late Stage Development, Diabetes and Endocrinology
Merck Research Laboratories
Cell: (b) (6)

Office: 732-594-8509
Email: peter.stein@merck.com

Notice: This e-mail message, together with any attachments, contains information of Merck & Co., Inc. (2000 Galloping Hill Road, Kenilworth, New Jersey, USA 07033), and/or its affiliates Direct contact information for affiliates is available at http://www.merck.com/contact/contacts.html) that may be confidential, proprietary copyrighted and/or legally privileged. It is intended solely for the use of the individual or entity named on this message. If you are not the intended recipient, and have received this message in error, please notify us immediately by reply e-mail and then delete it from your system.

From: Wholley, David (FNIH) [T]
Sent: Fri, 16 Dec 2016 11:43:20 -0500
To: Collins, Francis (NIH/OD) [E]
Subject: RE: Extended EC - How did you think it went?

Well, yes that has always been a challenge on these calls. I think maybe T2D got no questions because it is what it is, and what it is seems to be going pretty well. I do think teeing up or planting a specific question or two will help, but so does calling people out by name (which is why I did that). Let's try both next time.

Yes, Lon's suggestion was interesting and may offer an opportunity. I think we should wait to see his proposal (I am happy to ping him) which you helpfully suggested, and certainly discuss at the EC. But I think the SCs also can help us by thinking through how they would answer what Lon ends up proposing along the lines of 1) what is the SC already planning to do in the area of functional validation? 2) how could that be expanded in a precompetitive context that would be suitable for AMP part 2? Thinking ahead, the other thing I think the SC's need to start thinking about this year is the sustainability strategy for these knowledge portal resources now that we are at the halfway point for AMP—ie. what happens in 2019 and beyond to what we've built.

Thanks, David

From: Collins, Francis (NIH/OD) [E]
Sent: Friday, December 16, 2016 11:30 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: RE: Extended EC - How did you think it went?

Seemed to go smoothly. Worried about the silence and slow response when we asked for comments (and never got any for T2D). Maybe in the future we need to cue a couple of questions for each project?

Lon's suggestion of having AMP evolve into target validation was interesting.

FC

From: Wholley, David (FNIH) [T]
Sent: Friday, December 16, 2016 10:03 AM
To: Collins, Francis (NIH/OD) [E] (b) (6)>
Subject: Extended EC - How did you think it went?

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
9650 Rockville Pike | Bethesda, MD 20814 | **fnih.org**
Direct (301) 594-6343 | dwholley@fnih.org



For 13 consecutive years, Charity Navigator has rated the FNIH as an organization that *exceeds industry standards.*

From: Wholley, David (FNIH) [T]
Sent: Fri, 15 Jul 2016 11:45:02 -0400
To: Rosema, Laura (NIH/OD) [E];Collins, Francis (NIH/OD) [E];Hudson, Kathy (NIH/OD) [E];Adam, Stacey (FNIH) [T]
Cc: Baker, Rebecca (NIH/OD) [E];Rosema, Laura (NIH/OD) [E];Wolinetz, Carrie (NIH/OD) [E]
Subject: Re: Follow up: 7/13/16 PACT Status Meeting

(b) (4)

Sent from my BlackBerry 10 smartphone.

From: Rosema, Laura (NIH/OD) [E]
Sent: Thursday, July 14, 2016 1:37 PM
To: Collins, Francis (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]; Wholley, David (FNIH) [T]; Adam, Stacey (FNIH) [T]
Cc: Baker, Rebecca (NIH/OD) [E]; Rosema, Laura (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]
Subject: Follow up: 7/13/16 PACT Status Meeting

Good afternoon,

Thank you for meeting yesterday to discuss the next steps for PACT. I have attached the notes from our conversation. Suggested action items are below:

- Rebecca Baker to attend 7-20-16 meeting of the NCI Blue Ribbon Panel.
- Dr. Collins to set up a phone call for Friday with Doug Lowy, Jim Doroshow, David Wholley, Rebecca Baker and Laura Rosema to get information from NCI on the questions outlined (in notes).
- Laura Rosema to send industry participants the consolidated notes from the phone calls during June.
- (b) (4)
- Laura Rosema and Rebecca Baker will compile an update for the Foundations that expressed interest in PACT

Please reach out to me or Rebecca Baker if you have any edits or questions.

Best,
Laura

Laura S. Rosema, PhD
Health Scientist/AAAS Fellow
Office of Science Policy
Office of the Director
National Institutes of Health
Ph (b) (6)

(b) (6)

From: Wholley, David (FNIH) [T]
Sent: Tue, 16 Aug 2016 07:52:43 -0400
To: Collins, Francis (NIH/OD) [E]
Cc: Boskent, Celeste (NIH/OD) [E];Wood, Gretchen (NIH/OD) [E];Di Mantova, Emma (NIH/OD) [E];Melencio, Cheryl (FNIH) [T];Gadbois, Ellen (NIH/OD) [E]
Subject: Re: Friday August 26 AMP EC call

Absolutely. Will send to you first for review.
Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Monday, August 15, 2016 9:55 PM
To: Wholley, David (FNIH) [T]
Cc: Boskent, Celeste (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Di Mantova, Emma (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]; Gadbois, Ellen (NIH/OD) [E]
Subject: RE: Friday August 26 AMP EC call

I knew that August would be challenging. Could we consider doing the update by e-mail this one time, and then asking everyone to make it a priority to join for the September EC?

FC

From: Wholley, David (FNIH) [T]
Sent: Monday, August 15, 2016 2:33 PM
To: Collins, Francis (NIH/OD) [E]
Cc: Boskent, Celeste (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Di Mantova, Emma (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]; Gadbois, Ellen (NIH/OD) [E]
Subject: Friday August 26 AMP EC call

Francis, as usual we have been monitoring prospective attendance for the EC meeting at the end of this month. So far we will be missing Mikael Dolsten (driving his daughter to college) and Francis Cuss (on a plane). Everyone else seems to be OK so far. Please let me know how you would like to approach this. Thanks, David

From: Wholley, David (FNIH) [T]
Sent: Thu, 10 Nov 2016 14:47:11 -0500
To: Collins, Francis (NIH/OD) [E]
Subject: RE: Hever Group...Update

Sure. How do you want the updates? A set of slides (1-2 for each area)? Or just some bullets in an email?

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, November 10, 2016 2:38 PM
To: Green, Eric (NIH/NHGRI) [E] <egreen@nhgri.nih.gov>; Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: FW: Hever Group...Update

Hi Eric and David,

See query below from Trevor Jones of the Hever Group.

Eric, can you provide any update on item 1? There was some discussion about inviting pharma reps to a discussion of how ClinGen was evolving. Did anything come of that?

David, can you get staff to provide bullets to answer the AMP and PACT questions?

I'll deal with the rest.

FC

From: Prof Trevor M Jones CBE [mailto:trevor.m.jones@btinternet.com]
Sent: Thursday, November 10, 2016 10:24 AM
To: Collins, Francis (NIH/OD) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6)
Subject: Hever Group...Update

Francis

You will remember that at our Hever meeting in April in NYC we discussed the "Diagnostics Initiative" and you updated the meeting on several key NIH projects

I am planning to send an update to those attending the Meeting and wonder whether you could let me have one or two "bullets " on each of the Action points listed below ?

My summary slides were as follows

---

1. **Diagnnostics Initiative**

- Principal objective is to move from single Dx profiling to approved Multiplex assays as a prelude to full
  DNA sequencing, proteomic ,transcriptomics.
- NIH ClinGen database curates literature and seeks to identify valid profiles
  ...Needs input from Hever initiative
- Plus continuing the discussion on the regulatory complexities
  e.g. peri/post-LOE drugs

ACTION NIH to examine possibility of hosting a meeting to review current projects / progress.

If so… poll interest of Hever members to participate .

FrC

---

2. NIH Update

- **AMP 3 projects**
  - Alzheimer's disease
  – Autoimmune disorders (rheumatoid arthritis and systemic lupus erythematosus)
  – Type 2 diabetes

  Possible New project proposals ……Parkinson's Disease
  ? Antibiotic Resistance Medicines and vaccines, schizophrenia ,others

FrC

- **National Cancer Moonshot**
  Industry (and Academia etc) being consulted re establishment of and priorities
  for Partnership for accelerating cancer therapies PACT

FrC

- **Precision Medicine Cohort (PMI Cohort)**
  Target is to enrol 1m (could be more !) by 2019
  Good links to UK Biobank
  34 longitudinal genomics data bases globally (with >100,000 subjects)
  …need to determine who might curate /combine the data

FrC

Best personal regards
Trevor

Prof Trevor M Jones CBE FMedSci

From: Wholley, David (FNIH) [T]
Sent: Mon, 28 Nov 2016 11:12:33 -0500
To: Sutherland, Margaret (NIH/NINDS) [E];Koroshetz, Walter (NIH/NINDS) [E]
Cc: Collins, Francis (NIH/OD) [E];Wolf-Rodda, Julie (FNIH) [T];Canet-Aviles, Rosa (FNIH) [T]
Subject: Status of AMP-PD funding
Attachments: Status update FNIH AMP PD funding.xlsx

Marg and Walter:
Wanted to give you an update on this as we spoke with (b) (4) during the week before the holiday. Bottom line is that we still have hope but will need at least three of our remaining prospects to fall our way in order to fund the full base case (b) (4)

(b) (4)

I have attached a table that Rosa Canet-Aviles put together summarizing the status of the entire effort to date.

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
9650 Rockville Pike | Bethesda, MD 20814 | **fnih.org**
Direct (301) 594-6343 | dwholley@fnih.org



For 13 consecutive years, Charity Navigator has rated the FNIH as an organization that *exceeds industry standards.*


(b) (4), (b) (5)

From: Wholley, David (FNIH) [T]
Sent: Wed, 14 Dec 2016 11:48:35 -0500
To: Collins, Francis (NIH/OD) [E]
Subject: RE: slides

Thanks, will make the suggestion

From: Collins, Francis (NIH/OD) [E]
Sent: Wednesday, December 14, 2016 9:52 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: RE: slides

Much better, though I think it would be better to drop slide 4.

From: Wholley, David (FNIH) [T]
Sent: Wednesday, December 14, 2016 9:18 AM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Subject: FW: slides

Does this look better? (Outside of the question mark in the header for the first slide...)

From: Koroshetz, Walter (NIH/NINDS) [E]
Sent: Wednesday, December 14, 2016 8:17 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Sutherland, Margaret (NIH/NINDS) [E] (b) (6)>
Subject: slides

Thanks. This looks good. I made a few more edits to simplify further.
walter

From: Wholley, David (FNIH) [T]
Sent: Fri, 23 Sep 2016 09:52:43 -0400
To: Collins, Francis (NIH/OD) [E]
Subject: RE: time crunch

BTW we warned AD and T2D folks in advance that they might not have much time so they were OK with it. (We also coached the PD presenters, cut their slides in half, but well, you know…) I think it all worked out OK.

From: Collins, Francis (NIH/OD) [E]
Sent: Friday, September 23, 2016 8:34 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: time crunch

PD presentation is terrific, but we will need to hold discussion tightly (stop at 8:40?) or we'll never get to RA/SLE. T2D and AD may get left out all together.

From: Wholley, David (FNIH) [T]
Sent: Thu, 22 Dec 2016 11:59:12 -0500
To: Collins, Francis (NIH/OD) [E]
Cc: Gadbois, Ellen (NIH/OD) [E];Baker, Rebecca (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E]
Subject: RE: Zerhouni

OK, we'll keep our options open then—hopefully we will not end up with a split with some companies supporting proposal 1, some proposal 2, and not enough on either side. Would you like to let Walter know?

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, December 22, 2016 11:14 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Gadbois, Ellen (NIH/OD) [E] (b) (6)>; Baker, Rebecca (NIH/OD) [E] (b) (6)>; Tabak, Lawrence (NIH/OD) [E] (b) (6)
Subject: RE: Zerhouni

Hi David,

I just spoke with Elias. He had not yet been pitched by Rita – various Sanofi intensities have gotten in the way.

So I gave him a rough outline of initiatives 1 and 2. Interestingly, he was particularly intrigued by initiative 1 – and described recent meetings with Thomas Sudhof that emphasized how important it is to consider the individual genetic and epigenetic differences between iPS lines. Elias thought working out those issues, and developing better standards for iPS differentiation into neurons, would be a highly appropriate topic for an international symposium, and for an AMP effort. He said less about the biomarkers project, though he wasn't negative.

We should check back after the first of the year, when Rita has given him the full presentation.

FC

From: Wholley, David (FNIH) [T]
Sent: Wednesday, December 21, 2016 5:20 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Subject: RE: Zerhouni

Francis,

(b) (4)

(b) (4)

David

From: Collins, Francis (NIH/OD) [E]
Sent: Wednesday, December 21, 2016 4:15 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: Zerhouni

I'll be speaking with Elias Z about a couple of things tomorrow – (b) (4)

FC

From: Wholley, David (FNIH) [T]
Sent: Wed, 21 Dec 2016 17:19:49 -0500
To: Collins, Francis (NIH/OD) [E]
Subject: RE: Zerhouni

Francis,

(b) (4)

David

From: Collins, Francis (NIH/OD) [E]
Sent: Wednesday, December 21, 2016 4:15 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: Zerhouni

I'll be speaking with Elias Z about a couple of things tomorrow – (b) (4)

FC

From: Wholley, David (FNIH) [T]
Sent: Fri, 23 Dec 2016 10:50:38 -0500
To: Koroshetz, Walter (NIH/NINDS) [E];Collins, Francis (NIH/OD) [E]
Cc: Gadbois, Ellen (NIH/OD) [E];Baker, Rebecca (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Sutherland, Margaret (NIH/NINDS) [E]
Subject: RE: Zerhouni

Thanks, Walter. I agree for now we should continue to go after funding for both projects, though I think we should signal some flexibility where needed that we will entertain some kind of split proposal if that is the way things line up. From what I am seeing below, if that were to happen, you'd be willing to entertain funding half of whatever the revised plan(s) look like. We can figure out the rest depending on what we hear from the remaining prospects after the holidays...appreciate the continued patience and support.

Regards, David

From: Koroshetz, Walter (NIH/NINDS) [E]
Sent: Thursday, December 22, 2016 7:20 PM
To: Collins, Francis (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Gadbois, Ellen (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6)>; Sutherland, Margaret (NIH/NINDS) [E] (b) (6)
Subject: RE: Zerhouni

Thanks. We can certainly look at alternatives. If funds were substantial wouldn't be a problem steering some to project 1 and others to project 2. I feel that from NINDS point of view something close to a 50/50 split is defensible in that it leverages our funds enough to support directing them to PD as opposed to the free for all of RPGs that includes all of our 200-400 disorders.

Marg can comment but I think:
Project 1 can be scaled in the sense that the number of mutations/risk alleles studied in the IPSC assays can toggle up or down. Would not scale down the intensity of the phenotyping though.

Project 2 can be scaled, ie., to limit intensive focus on brain tissue ± CSF next.

There is some beauty to prosecuting both projects to see where the data intersect.

Walter

N.B.

(b) (5)

Also- We funded Ole Isaacson to run the PD portion of our IPSC consortia (PD, HD, ALS ran from ~2010-2015) where we had a PPP to standardize the differentiation of neurons from IPSCs. So he might want to do this himself at Pfizer.

FYI- Attached recent paper on the AMP AD brain project. Can see that doing something similar, or better yet a single cell analysis, could be quite interesting.

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, December 22, 2016 12:05 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Koroshetz, Walter (NIH/NINDS) [E] (b) (6)
Cc: Gadbois, Ellen (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6)
Subject: RE: Zerhouni

Looping in Walter.

From: Wholley, David (FNIH) [T]
Sent: Thursday, December 22, 2016 11:59 AM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Gadbois, Ellen (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6)
Subject: RE: Zerhouni

OK, we'll keep our options open then—hopefully we will not end up with a split with some companies supporting proposal 1, some proposal 2, and not enough on either side. Would you like to let Walter know?

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, December 22, 2016 11:14 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Gadbois, Ellen (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6)
Subject: RE: Zerhouni

Hi David,

I just spoke with Elias. He had not yet been pitched by Rita - (b) (4)

So I gave him a rough outline of initiatives 1 and 2. Interestingly, he was particularly intrigued by initiative 1 – and described recent meetings with Thomas Sudhof that emphasized how important it is to consider the individual genetic and epigenetic differences between iPS lines. Elias thought working out those issues, and developing better standards for iPS differentiation into neurons, would be a highly appropriate topic for an international symposium, and for an AMP effort. He said less about the biomarkers project, though he wasn't negative.

We should check back after the first of the year, when Rita has given him the full presentation.

FC

From: Wholley, David (FNIH) [T]
Sent: Wednesday, December 21, 2016 5:20 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)>
Subject: RE: Zerhouni

Francis,

(b) (4)

David

From: Collins, Francis (NIH/OD) [E]
Sent: Wednesday, December 21, 2016 4:15 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: Zerhouni

I'll be speaking with Elias Z about a couple of things tomorrow – (b) (4)

FC

From: Melencio, Cheryl (FNIH) [T] on behalf of Wholley, David (FNIH) [T]
Sent: Mon, 8 Aug 2016 13:19:12 -0400
To: Buckholtz, Neil (NIH/NIA) [C];Carter, Robert (NIH/NIAMS) [E];Collins, Francis (NIH/OD) [E];Cuss, Francis;Decker, Mike;Dolsten, Mikael;Gadbois, Ellen (NIH/OD) [E];Hodes, Richard (NIH/NIA) [E];Hodge, Martin;Hudson, Kathy (NIH/OD) [E];Katz, Stephen I. (NIH/NIAMS) [E];Koroshetz, Walter (NIH/NINDS) [E];Lea, Allison (NIH/OD) [C];Lifton, Richard;Lundberg, Jan;Paltoo, Dina (NIH/OD) [E];Rodgers, Griffin (NIH/NIDDK) [E];Ryan, Laurie (NIH/NIA) [E];Serrate-Sztein, Susana (NIH/NIAMS) [E];Smith, Philip (NIH/NIDDK) [E];Stein, Peter;Sutherland, Margaret (NIH/NINDS) [E];Terry, Sharon MA;Petanceska, Suzana (NIH/NIA) [E];'morten.sogaard@pfizer.com'
Cc: Hoffmann, Steve (FNIH) [T];Canet-Aviles, Rosa (FNIH) [T];Spear, Nicole (FNIH) [T];Whitaker, Sanya (FNIH) [T];Wholley, David (FNIH) [T]
Subject: Response to Allen Roses AMP proposal
Attachments: FNIH AMP reply to Roses Letter 080816.doc

Dear AMP Executive Committee Members:

Please see attached my response to the research proposal advanced for AMP by Allen Roses, which we discussed on our last EC call July 29. Please let me know if you have any suggested changes by 3PM on Wednesday, August 10.

Regards,

David Wholley
Director, Research Partnerships
FNIH

FNIH
Foundation for the
National Institutes of Health

August 8, 2016

Allen D. Roses, M.D.
President & CEO
Semillon Pharmaceuticals
P.O. Box 110395
Research Triangle Park, NC 27709

Dear Dr. Roses:

I am responding to your letter of July 22 addressed to Laurie Ryan at the National Institute on Aging requesting support from the Accelerating Medicines Partnership (AMP) for a proposed treatment trial in patients with Mild Cognitive Impairment. I work for the Foundation for the National Institutes of Health (FNIH), which manages AMP and is responsible for managing review and evaluation of new research proposals by the AMP Executive Committee.

The Executive Committee, which is co-chaired by Francis Collins (NIH) and Mikael Dolsten (Pfizer), has discussed your proposal and has concluded that it is not a fit for AMP, since AMP is focused exclusively on precompetitive target identification and validation research, and does not fund specific trials. We recommend you pursue one of the number of other government-sponsored or private sector funding mechanisms available for the type of research you have proposed.

I can be reached at dwholley@fnih.org or 301-594-6343 should you have any further questions.

Sincerely,

David Wholley

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health

Cc: Francis Collins, NIH
Mikael Dolsten, Pfizer
Laurie Ryan, NIA

9650 Rockville Pike, Bethesda, MD 20814
main 301.402.5311 fax 301.480.2752

From: Wholley, David (FNIH) [T]
Sent: Fri, 28 Jul 2017 17:07:07 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Wood, Gretchen (NIH/OD) [E];Wolinetz, Carrie (NIH/OD) [E];Baker, Rebecca (NIH/OD) [E];Adam, Stacey (FNIH) [T];Lowy, Douglas (NIH/NCI) [E];Doroshow, James (NIH/NCI) [E];Tabak, Lawrence (NIH/OD) [E]
Subject: (b) (4)

(b) (4)

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Wholley, David (FNIH) [T]
Sent: Thu, 5 Oct 2017 23:06:42 +0000
To: Collins, Francis (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Hodes, Richard (NIH/NIA) [E]
Subject: Changes at Lilly--Lundberg retiring

In case you had not heard:

https://www.reuters.com/article/lilly-cfo/lilly-names-new-cfo-replaces-head-of-rd-in-management-shakeup-idUSL2N1MA0SE

From: Wholley, David (FNIH) [T]
Sent: Fri, 14 Jul 2017 09:33:53 -0400
To: Collins, Francis (NIH/OD) [E];Lowy, Douglas (NIH/NCI) [E];Doroshow, James (NIH/NCI) [E];Tabak, Lawrence (NIH/OD) [E]
Cc: Wolinetz, Carrie (NIH/OD) [E];Baker, Rebecca (NIH/OD) [E]
Subject: Discussion with Joanne Lager at Sanofi - confidential

Dear All—in keeping with our promise to update you on PACT prospects as we hear about them: Stacey Adam and I just got off the phone with Joanne Lager, VP and Head of Oncology Development at Sanofi. If you will recall this discussion has been a while in the making; Joanne had not been responsive to earlier emails but Lana Skirboll helped reestablish the connection. Joanne had therefore not already heard about the reduction in required funds or other changes in plan.

(b) (4)

(b) (4) I think this resonated somewhat, and the news that the required investment has been cut in half and that there is likely a prominent announcement opportunity resonated as well. Joanne is going to go back to her colleagues and see if this new perspective helps. She said she would check back in with us in two weeks, though she may not have the full answer by then.

I would say they are still in the doubtful column but the door remains open. Let's see if they walk through it.

Also – FYI for Doug and Jim and Larry: we had updated Francis on this yesterday, (b) (4)

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Wholley, David (FNIH) [T]
Sent: Thu, 17 Aug 2017 22:11:50 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Canet-Aviles, Rosa (FNIH) [T];Hoffmann, Steve (FNIH) [T];Vardanian, Lilit (FNIH) [T];Melencio, Cheryl (FNIH) [T];Wood, Gretchen (NIH/OD) [E];Di Mantova, Emma (NIH/OD) [E];Boskent, Celeste (NIH/OD) [E];NIHDirectorMeetings;Gadbois, Ellen (NIH/OD) [E];Lea, Allison (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E]
Subject: DRAFT August 25, 2017 AMP EC Meeting Slides and materials for tomorrow morning's pre-call
Attachments: AMP EC Slides August 25-DRAFT.pptx, Copy of AMP EC August 25 Attendee List.xlsx, 2017_06_30_AMP EEC teleconference final draft clean.docx, 2017_06_12_AMP EC teleconference draft.docx

Francis, all:
Here is the proposed slide deck along with meeting responses to date and minutes from our last EEC and EC meetings, for tomorrow morning's call. Sorry for sending this out so late but I was waiting on some late additions from a couple of the co-chairs.

Regards,
David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

Accelerating Medicines PartnershipExecutive Committee Update

25 August, 2017



FNIH
Foundation for the National Institutes of Health

Contents

(b) (5)

(b) (4), (b) (5)

Accelerating Medicines PartnershipParkinson's DiseaseProgram Development

FNIH

Foundation for the National Institutes of Health

NIH - 001554



(b) (4), (b) (5)

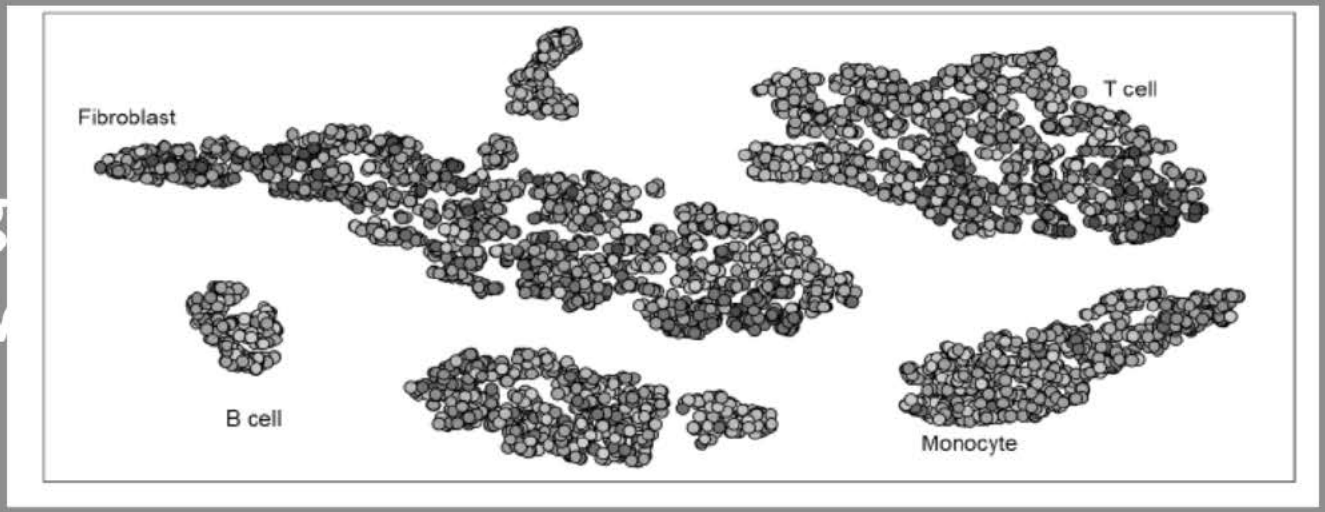
(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

Accelerating
Carter, NIAM



FNIH

Foundation for the
National Institutes of Health

NIH - 001560



(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

Accelerating Medicines PartnershipAlzheimer's Disease

FNIH

Foundation for the National Institutes of Health

NIH - 001567



(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

Accelerating Medicines PartnershipType 2 Diabetes

FNIH

Foundation for the
National Institutes of Health

NIH - 001578



(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

Upcoming EC meetings

- **Next MeetingAMP EC: Friday, October 27 from 7:00 am – 8:00 am AMP EEC: Friday, December 15 from 7:00 am – 8:30 am**

Name	Attendance	Response
Melencio, Cheryl (FNIH) [T]	Meeting Organizer	None
Buckholtz, Neil (NIH/NIA) [C]	Required Attendee	Accepted
Canet-Aviles, Rosa (FNIH) [T]	Required Attendee	Accepted
Carter, Robert (NIH/NIAMS) [E]	Required Attendee	Accepted
Collier, David	Required Attendee	Accepted
Collins, Francis (NIH/OD) [E]	Required Attendee	Accepted
Dolsten, Mikael	Required Attendee	Accepted
Gadbois, Ellen (NIH/OD) [E]	Required Attendee	Accepted
Hodes, Richard (NIH/NIA) [E]	Required Attendee	Accepted
Hodge, Martin	Required Attendee	Accepted
Hoffmann, Steve (FNIH) [T]	Required Attendee	Accepted
Hudson, Kathy (NIH/NLM) [V]	Required Attendee	Accepted
Katz, Stephen I. (NIH/NIAMS) [E]	Required Attendee	Accepted
Koroshetz, Walter (NIH/NINDS) [E]	Required Attendee	Accepted
Lea, Allison (NIH/OD) [E]	Required Attendee	Accepted
Lifton, Richard	Required Attendee	None
Lundberg, Jan	Required Attendee	Accepted
Paltoo, Dina (NIH/OD) [E]	Required Attendee	Accepted
Rodgers, Griffin (NIH/NIDDK) [E]	Required Attendee	Declined - on vacation
Ryan, Laurie (NIH/NIA) [E]	Required Attendee	Accepted
Serrate-Sztein, Susana (NIH/NIAMS) [E]	Required Attendee	Accepted
Smith, Philip (NIH/NIDDK) [E]	Required Attendee	Accepted
Sutherland, Margaret (NIH/NINDS) [E]	Required Attendee	Accepted
Tabak, Lawrence (NIH/OD) [E]	Required Attendee	None
Terry, Sharon	Required Attendee	Declined - on Sabbatical
Wholley, David (FNIH) [T]	Required Attendee	Accepted
Grabus, Sheri	Required Attendee	Accepted
Thomas, Melissa	Required Attendee	Accepted
Stoffels, Paul	Required Attendee	Accepted
Vardanian, Lilit	Required Attendee	Accepted
Petanceska, Suzana (NIH/NIA) [E]	Required Attendee	Accepted

Foundation for the National Institutes of Health (FNIH)
Accelerating Medicines Partnership (AMP)
Extended Executive Committee (EEC)
Teleconference Meeting Minutes

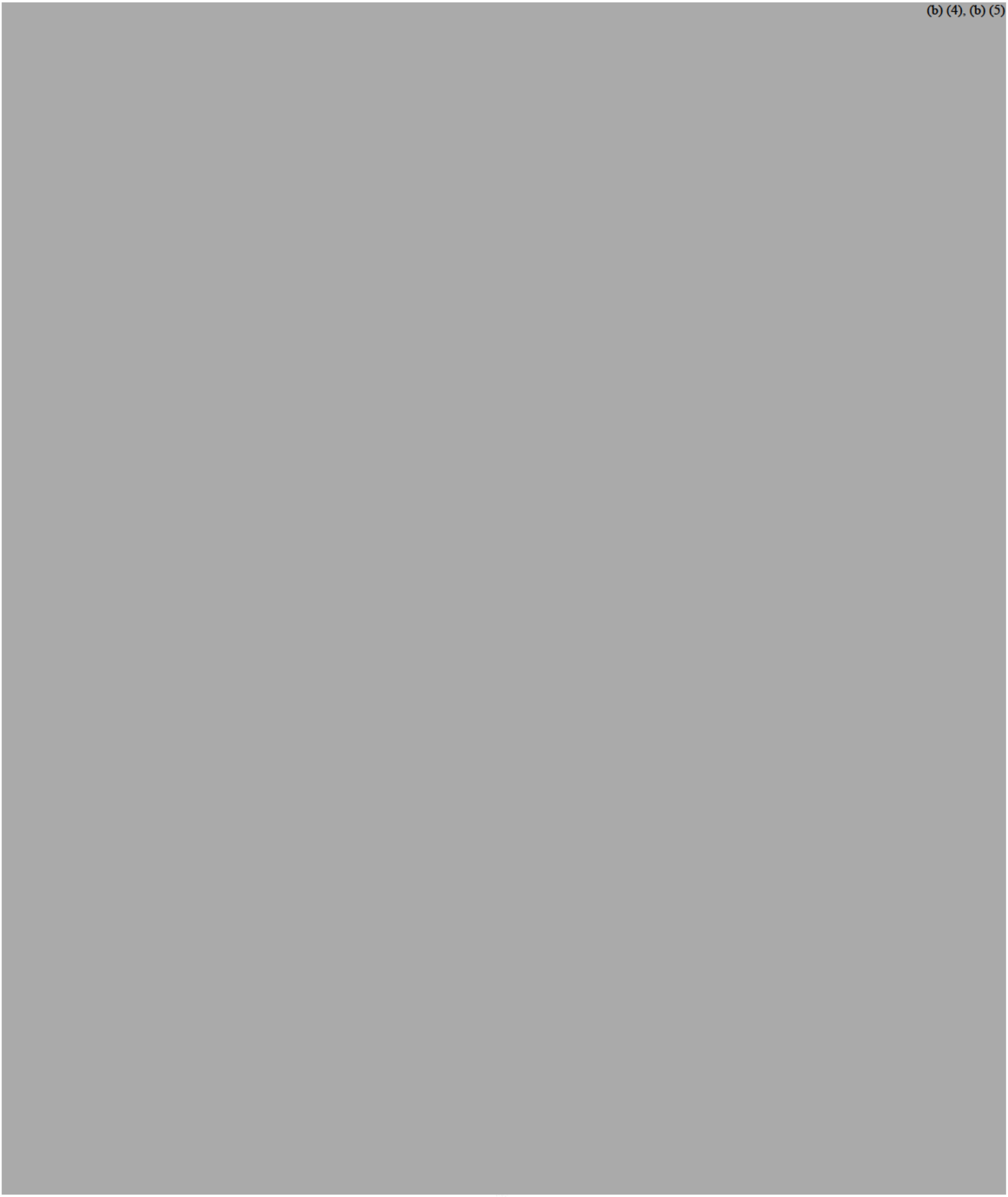
Friday, June 30, 2017
7:00 – 8:30 a.m. ET

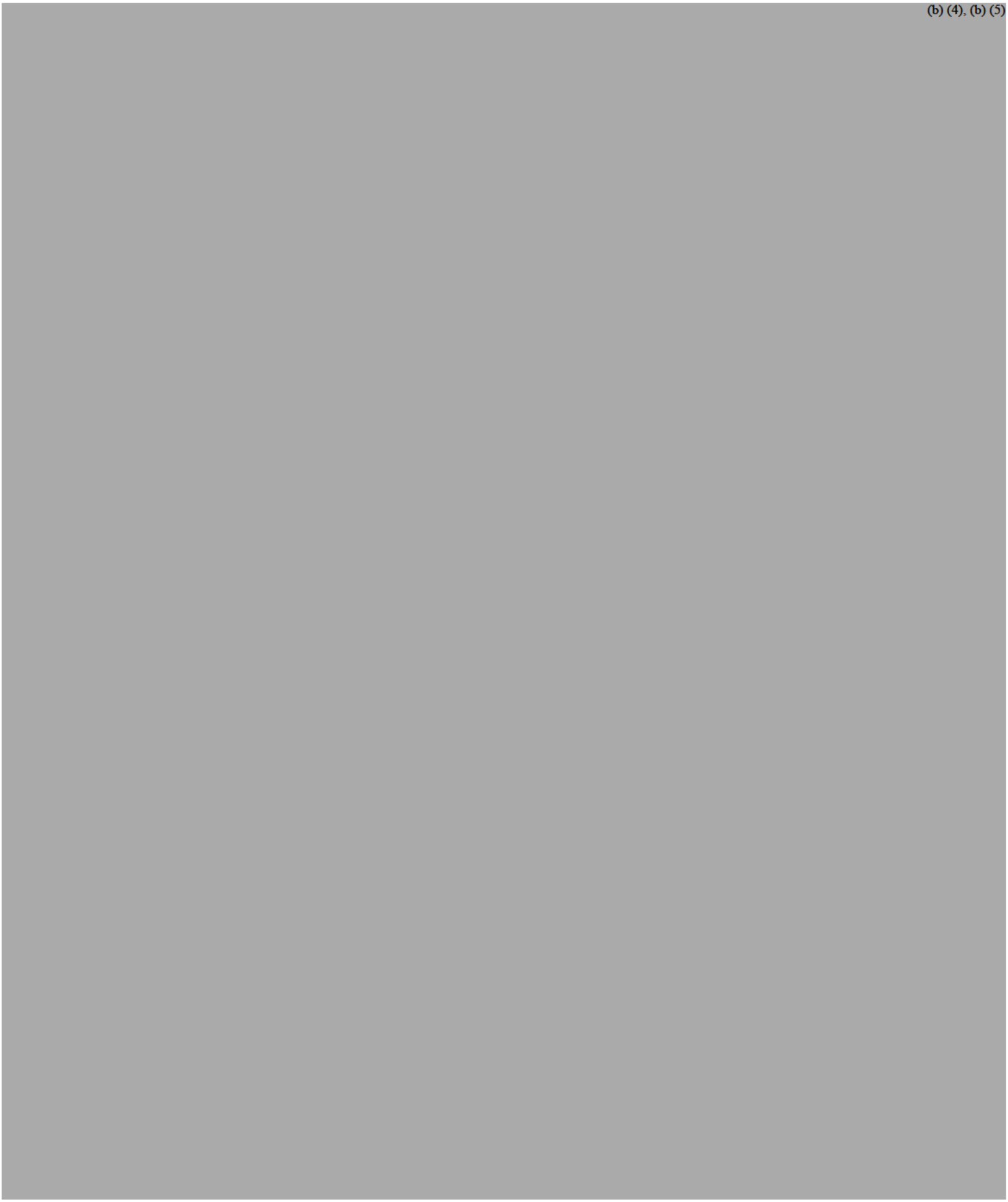
Participants

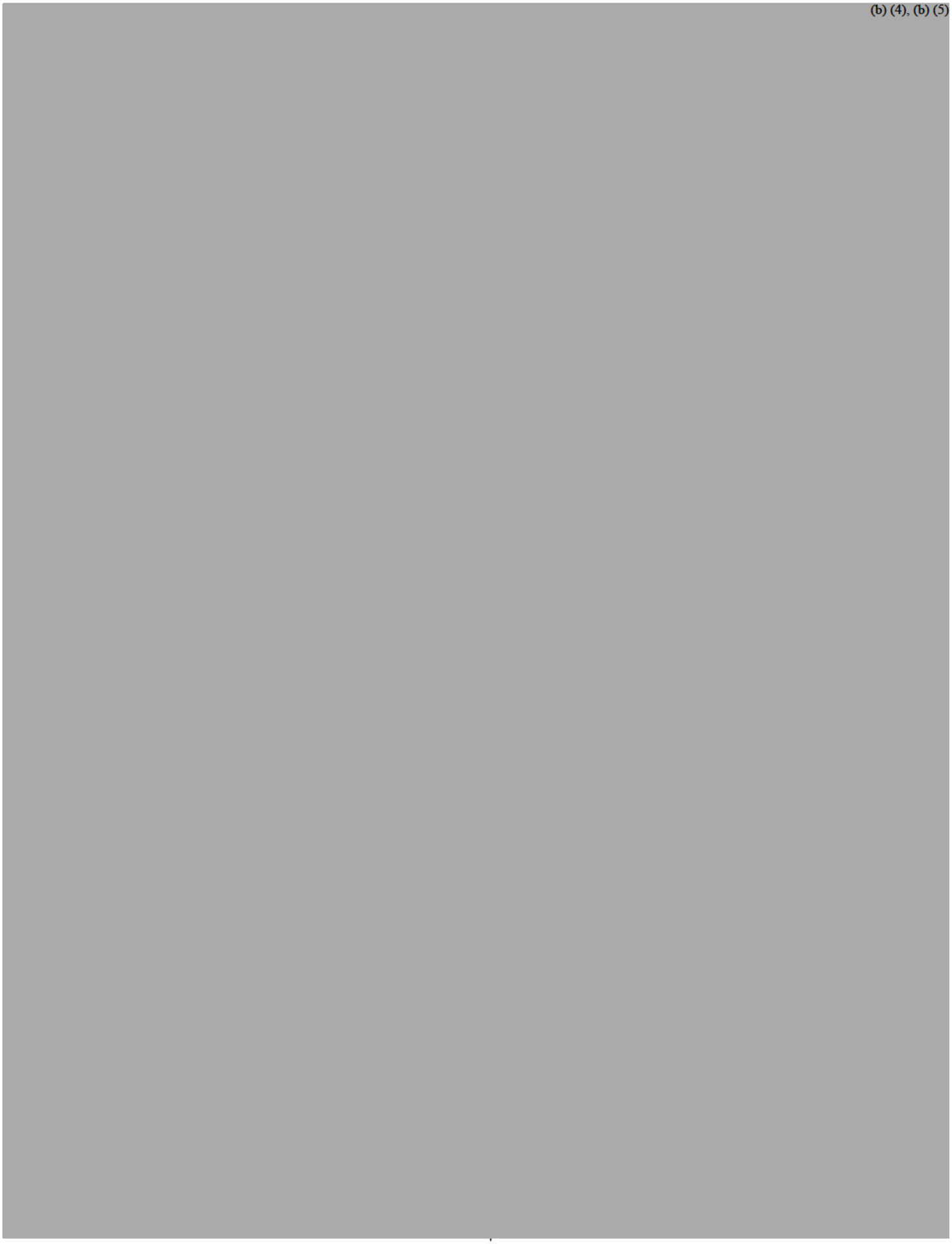
Salvatore Alesci (Takeda), Neil Buckholtz (NIH/NIA), Rosa Canet-Avilés (FNIH), Lon Cardon (GSK), Bob Carter (NIH/NIAMS), Francis Collins (NIH), Mary Collins (Lupus Research Alliance), Andrew Dahlem (Lilly), Mike Decker (AbbVie), Mikael Dolsten (Pfizer), Mark Erion (J&J), Ellen Goldmuntz (NIH/NIAID), James Hendrix (Alzheimer's Association), Richard Hodes (NIH/NIA), Steve Hoffmann (FNIH), Stephen Katz (NIH/NIAMS), Walter Koroshetz (NIH/NINDS), Joseph Miletich (Merck), Gary Nabel (Sanofi), Dina Paltoo (NIH), Griffin Rodgers (NIH/NIDDK), Daniel Rotrosen (NIH/NIAID), Laurie Ryan (NIH/NIA), Susana Serrate-Sztein (NIH/NIAMS), Phil Smith (NIH/NIDDK), Jim Sullivan (AbbVie), Marg Sutherland (NIH/NINDS), Larry Tabak (NIH), Melissa Thomas (Lilly), Lilit Vardanian (FNIH), David Wholley (FNIH), Janet Woodcock (FDA)

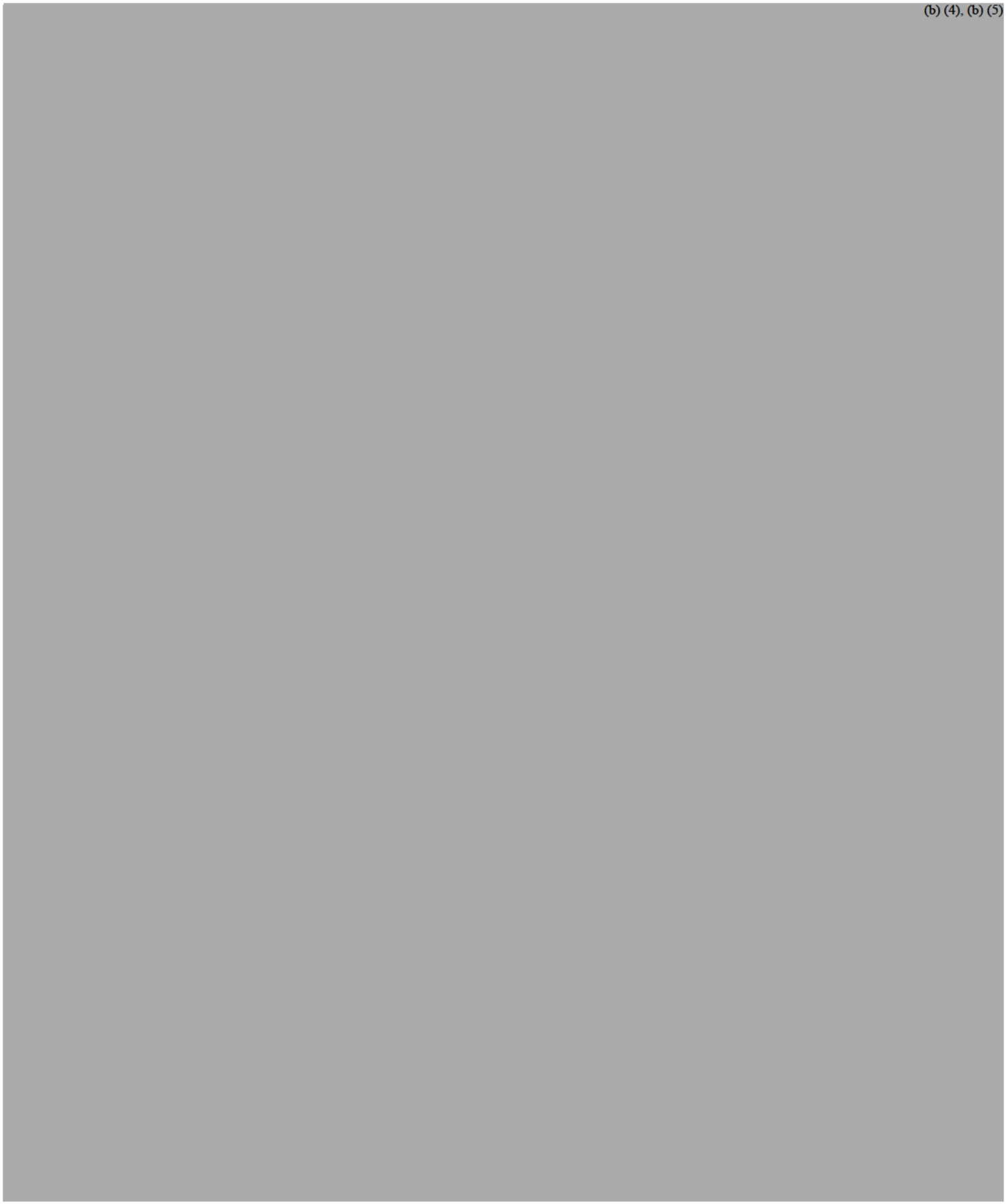
(b) (4), (b) (5)

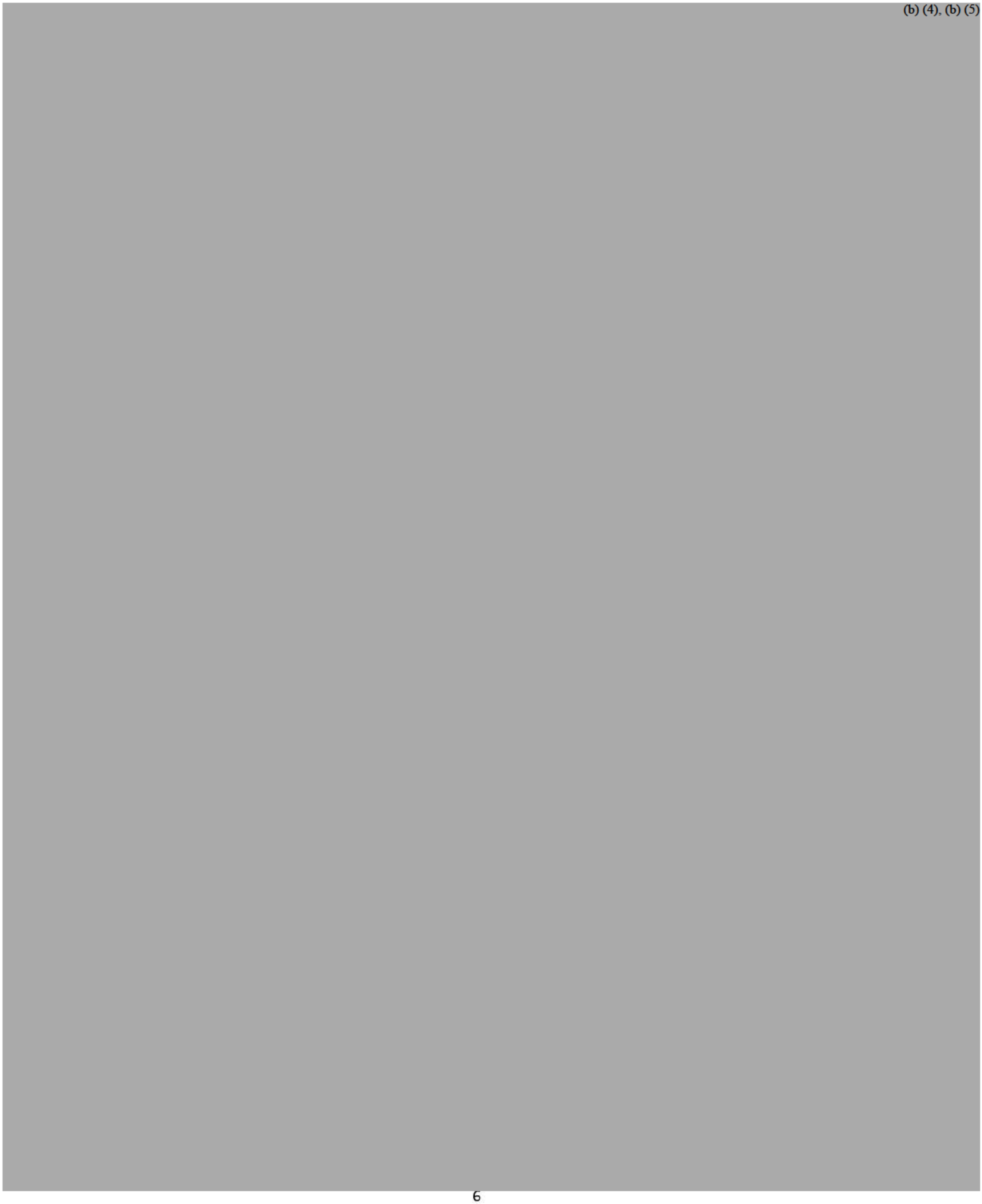
[redacted]






(b) (4), (b) (5)



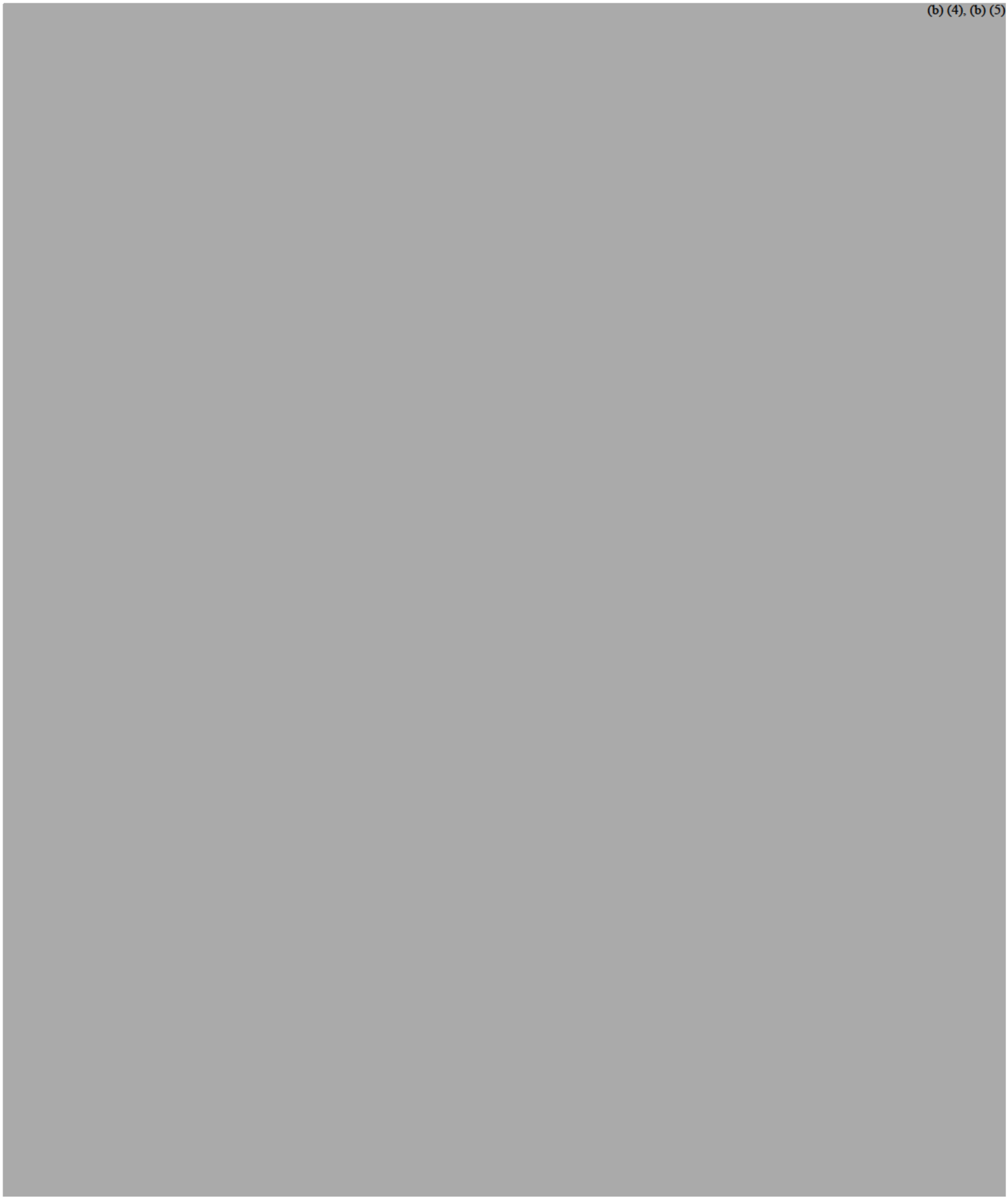

(b) (4), (b) (5)

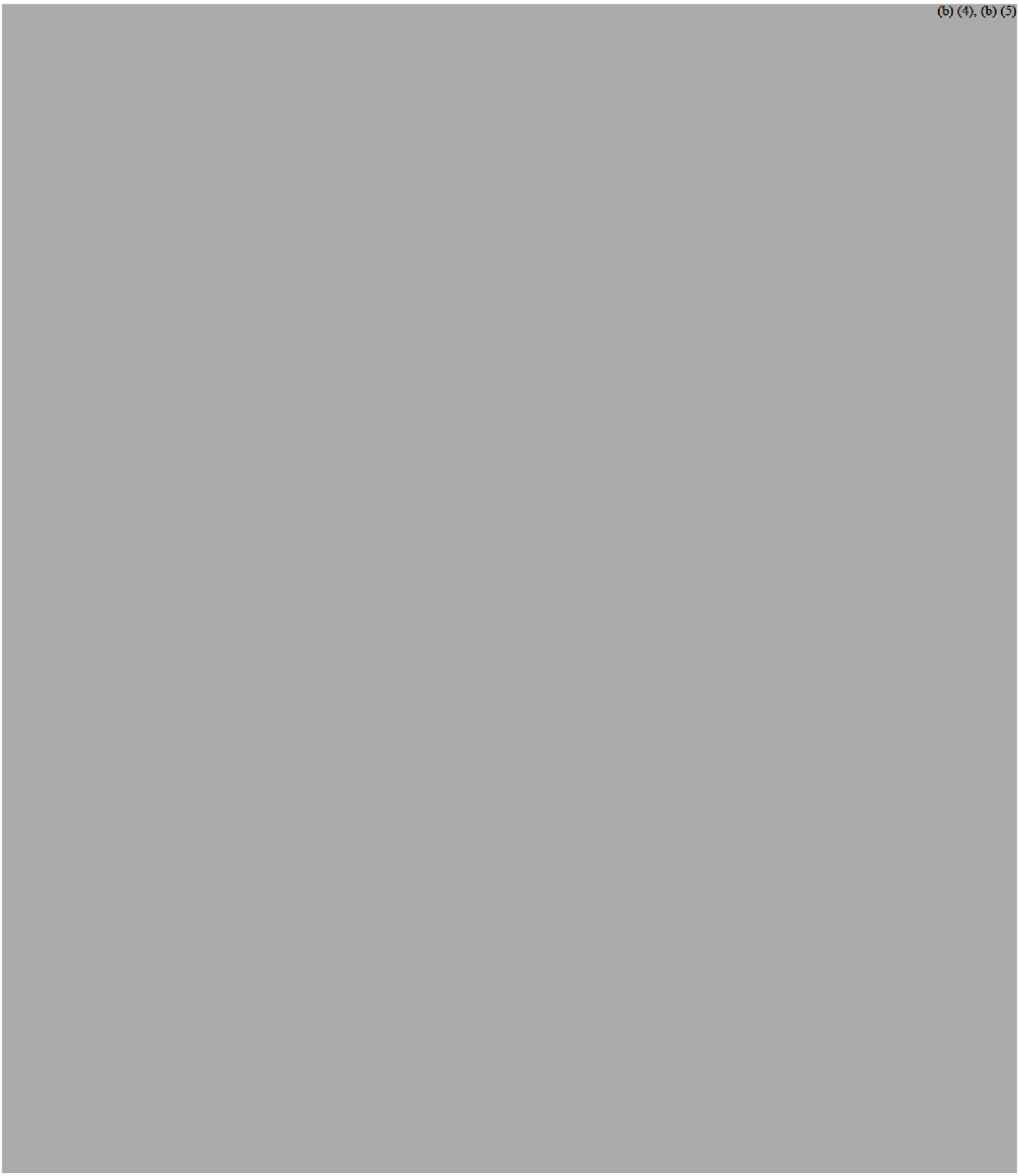
Foundation for the National Institutes of Health (FNIH)
Accelerating Medicines Partnership (AMP)
Executive Committee (EC)
Teleconference Meeting Minutes
Monday, June 12, 2017
7:00 – 8:00 a.m. ET

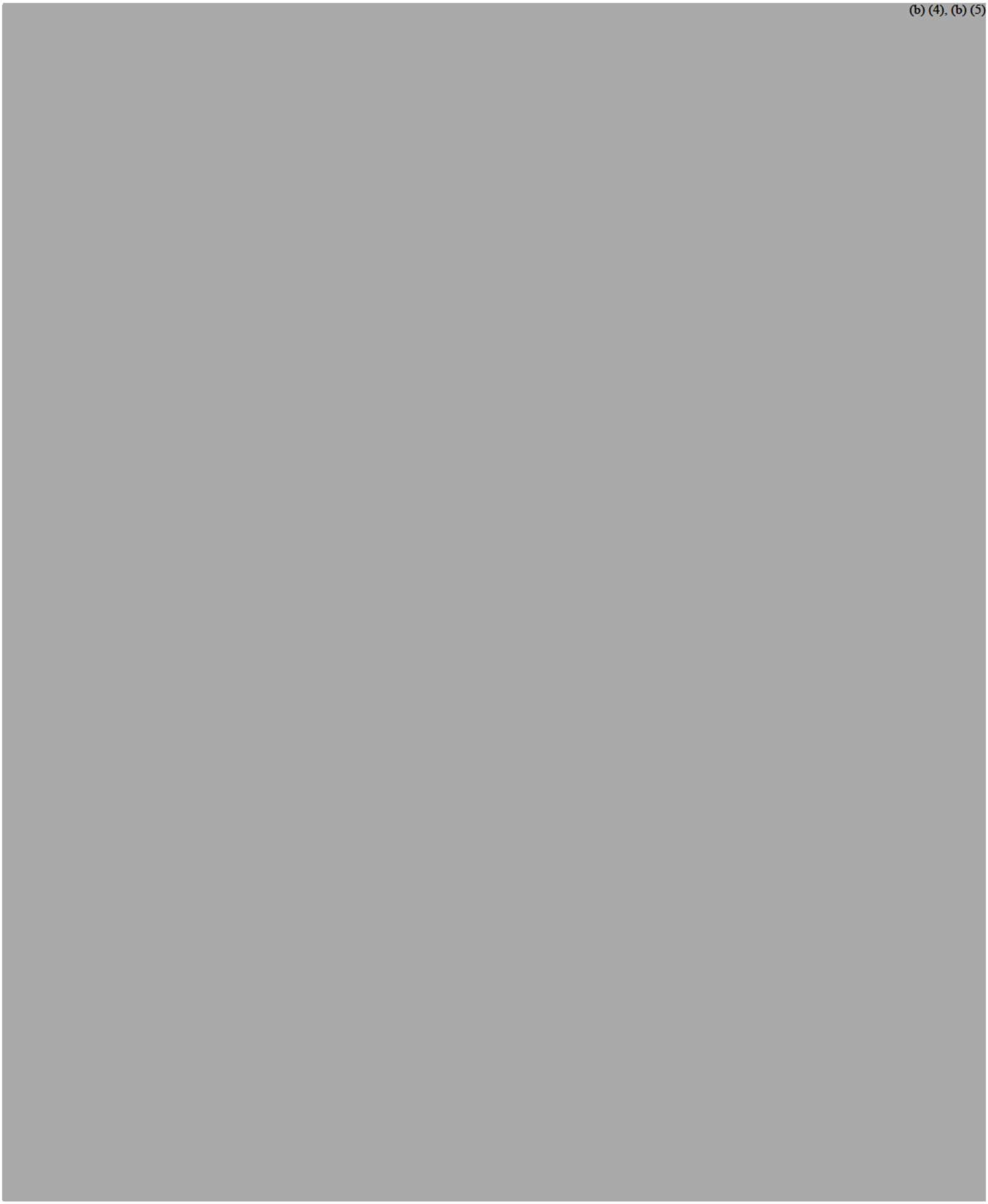
Participants
Neil Buckholtz (NIH/NIA), Rosa Canet-Avilés (FNIH), Bob Carter (NIH/NIAMS), Francis Collins (NIH), Michael Decker (AbbVie), Mikael Dolsten (Pfizer), Ellen Gadbois (NIH), Richard Hodes (NIH/NIA), Marty Hodge (Pfizer), Steve Hoffmann (FNIH), Stephen Katz (NIH/NIAMS), Walter Koroshetz (NIH/NINDS), Jan Lundberg (Lilly), Joseph Menetski (FNIH), Dina Paltoo (NIH), Laurie Ryan (NIH/NIA), Philip Smith (NIH/NIDDK), Paul Stoffels (J&J), Larry Tabak (NIH), Sharon Terry (Genetic Alliance), Melissa Thomas (Lilly), Lilit Vardanian (FNIH), David Wholley (FNIH)

(b) (4), (b) (5)








(b) (4), (b) (5)

[redacted]

From: Wholley, David (FNIH) [T]
Sent: Mon, 23 Oct 2017 00:50:39 +0000
To: McManus, Ayanna (NIH/OD) [E];Wood, Gretchen (NIH/OD) [E];Boskent, Celeste (NIH/OD) [E];Di Mantova, Emma (NIH/OD) [E];Collins, Francis (NIH/OD) [E]
Cc: Hoffmann, Steve (FNIH) [T];Menetski, Joseph (FNIH) [T];Vardanian, Lilit (FNIH) [T];Canet-Aviles, Rosa (FNIH) [T];Cush, Stephanie (FNIH) [T];Melencio, Cheryl (FNIH) [T];Morgan, Emily (FNIH) [T]
Subject: Draft of slides for discussion on tomorrow's AMP EC pre-call
Attachments: AMP EC Slides Oct 27-Draft.pptx, 2017_08_25_AMP EC teleconference final.docx
Importance: High

This is what I have so far for tomorrow's call. Still awaiting review/inputs from some of the co-chairs. Look forward to our discussion.

FYI I will be out of town at a family wedding on Friday October 27. Expect I will be able to call in and moderate the EC call, but if for any reason I am unable to (it will be 6AM where I am, and not a familiar environment) Joe Menetski is prepared to lead the call from the FNIH side without me.

Thanks, David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

Accelerating Medicines PartnershipExecutive Committee Update

27 October, 2017



FNIH
Foundation for the National Institutes of Health

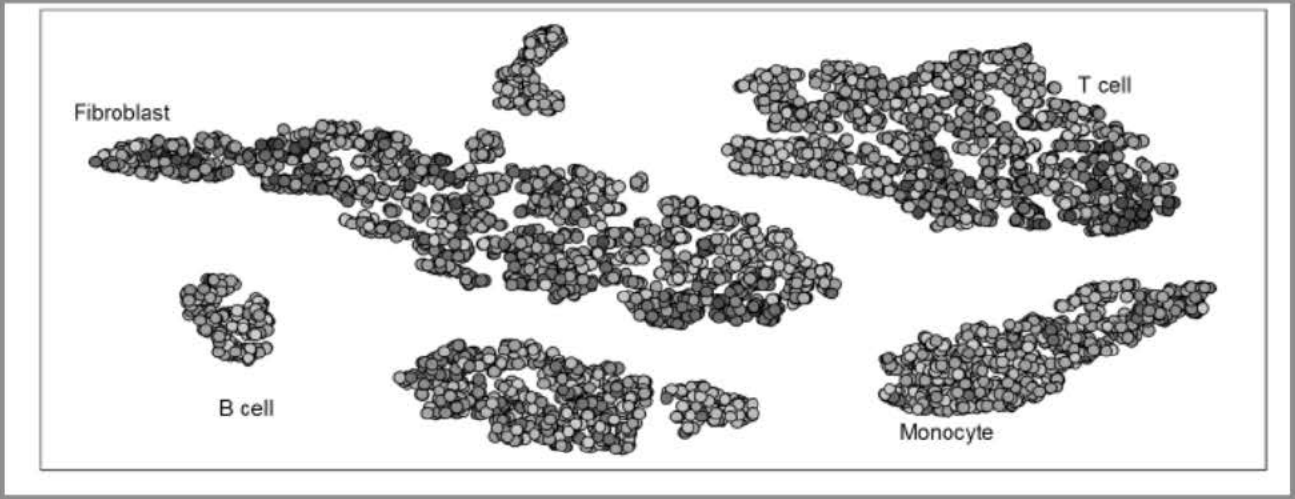
Contents

Update on AMP research initiatives Rheumatoid Arthritis/LupusAlzheimer's DiseaseType 2 DiabetesParkinson's Disease Planning for AMP Extended EC teleconference (12/15/17)

Action Items from the most recent EC and EEC meetings

From the 8/25 AMP EC meeting:No action items recorded

Accelerating Medicines PartnershipRA/SLE



FNIH

Foundation for the
National Institutes of Health

NIH - 001604



(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

Accelerating Medicines PartnershipAlzheimer's Disease

FNIH

Foundation for the National Institutes of Health

NIH - 001619



(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (5)

Accelerating Medicines PartnershipType 2 Diabetes

DRAFT slides awaiting first review by co-chairs

FNIH

Foundation for the National Institutes of Health

NIH - 001631



(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

Accelerating Medicines PartnershipParkinson's DiseaseProgram Development

FNIH

Foundation for the National Institutes of Health

NIH - 001641



(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

Upcoming EC meetings

- **Next MeetingAMP EEC: Friday, December 15 from 7:00 am – 8:30 am**

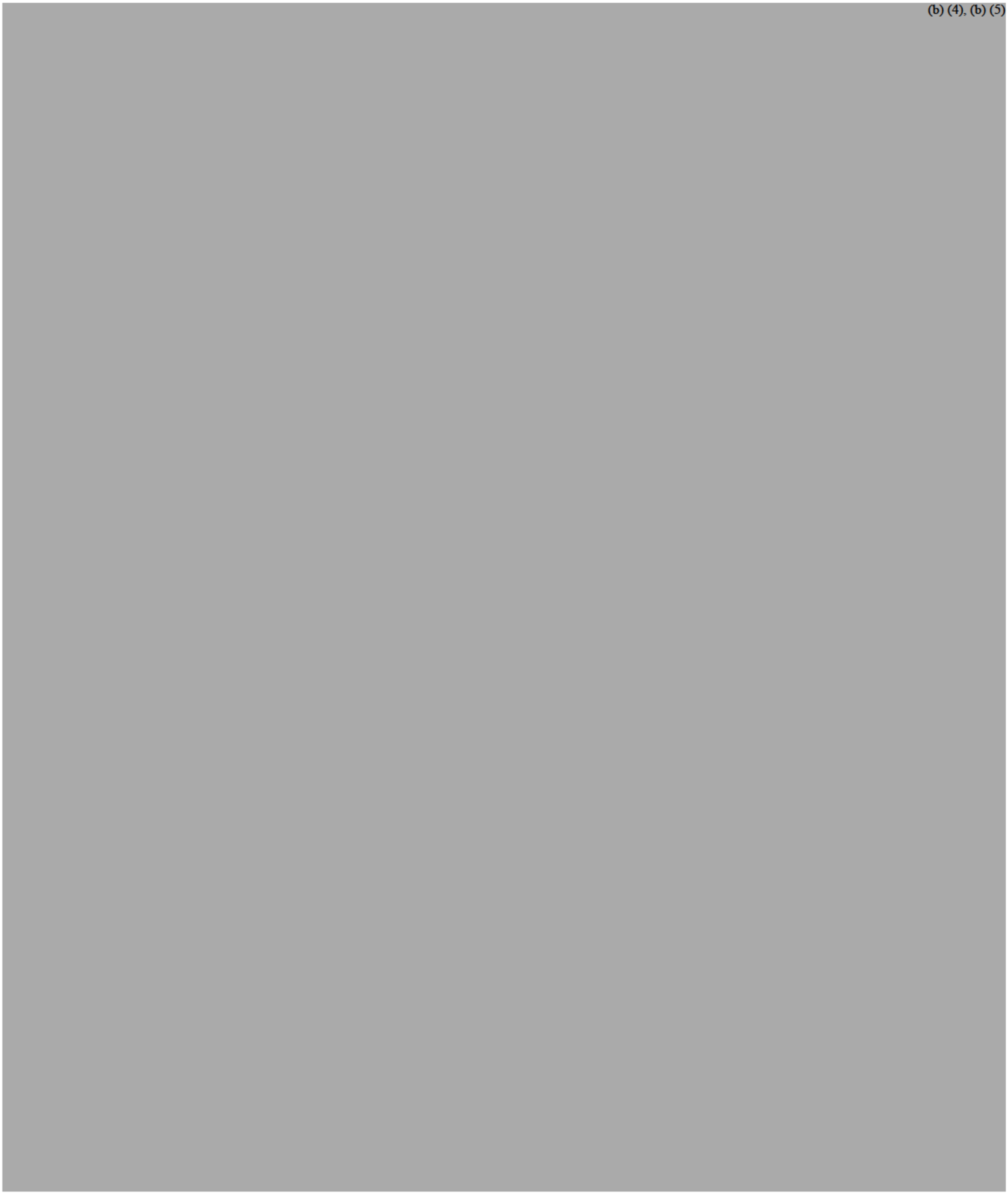
Foundation for the National Institutes of Health (FNIH)
Accelerating Medicines Partnership (AMP)
Executive Committee (EC)
Teleconference Meeting Minutes
Friday, August 25, 2017
7:00 – 8:00 a.m. ET

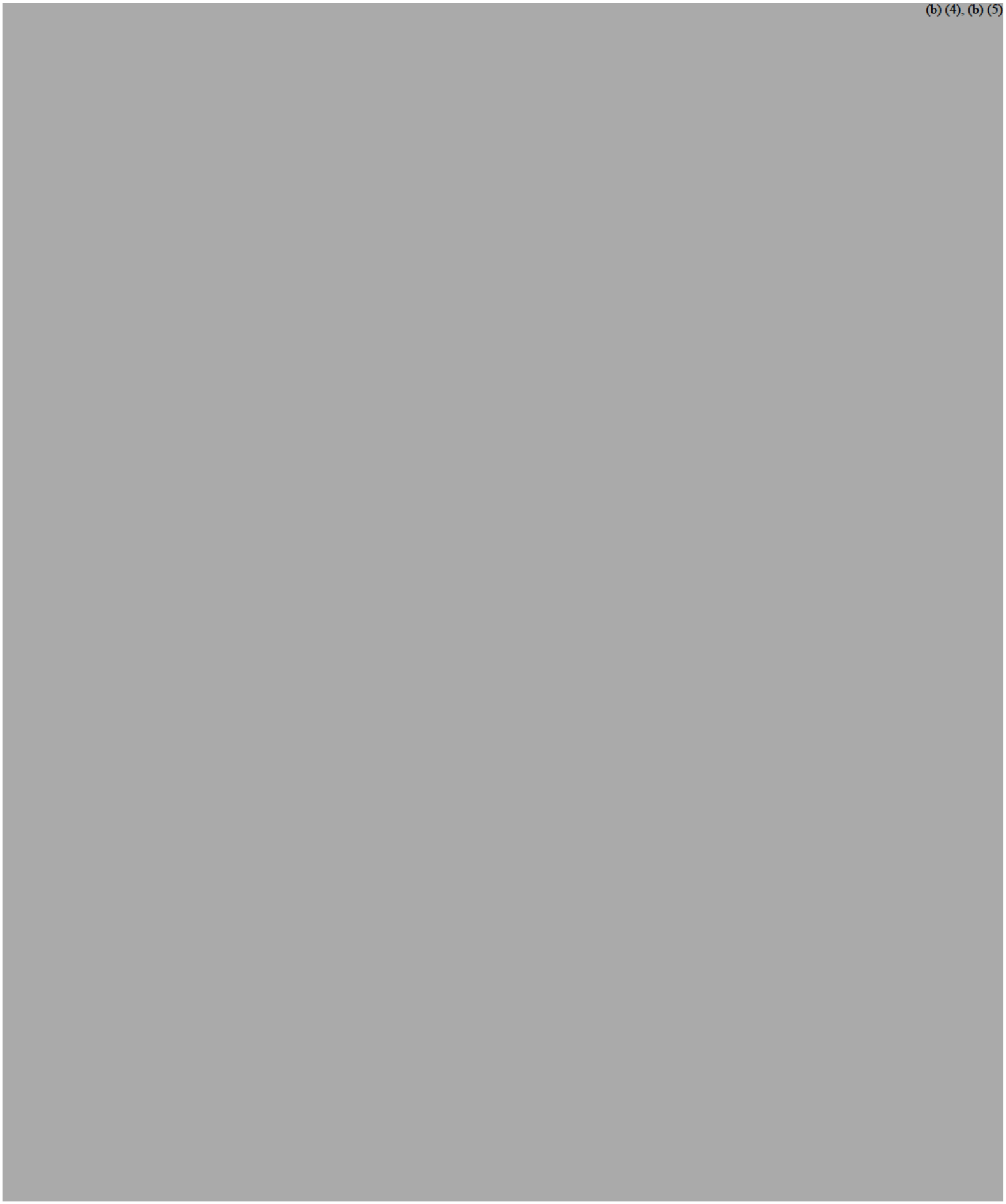
Participants
Michael Biarnes (FNIH), Neil Buckholtz (NIH/NIA), Bob Carter (NIH/NIAMS), David Collier (Lilly), Francis Collins (NIH), Stephanie Cush (FNIH), Mikael Dolsten (Pfizer), Tanya Fischer (Sanofi), Richard Hodes (NIH/NIA), Marty Hodge (Pfizer), Steve Hoffmann (FNIH), Stephen Katz (NIH/NIAMS), Walter Koroshetz (NIH/NINDS), Allison Lea (NIH), Jan Lundberg (Lilly), Joseph Menetski (FNIH), Laurie Ryan (NIH/NIA), Susana Serrate-Sztein (NIH/NIAMS), Philip Smith (NIH/NIDDK), Margaret Sutherland (NIH/NINDS), Larry Tabak (NIH), Melissa Thomas (Lilly), Lilit Vardanian (FNIH), David Wholley (FNIH)

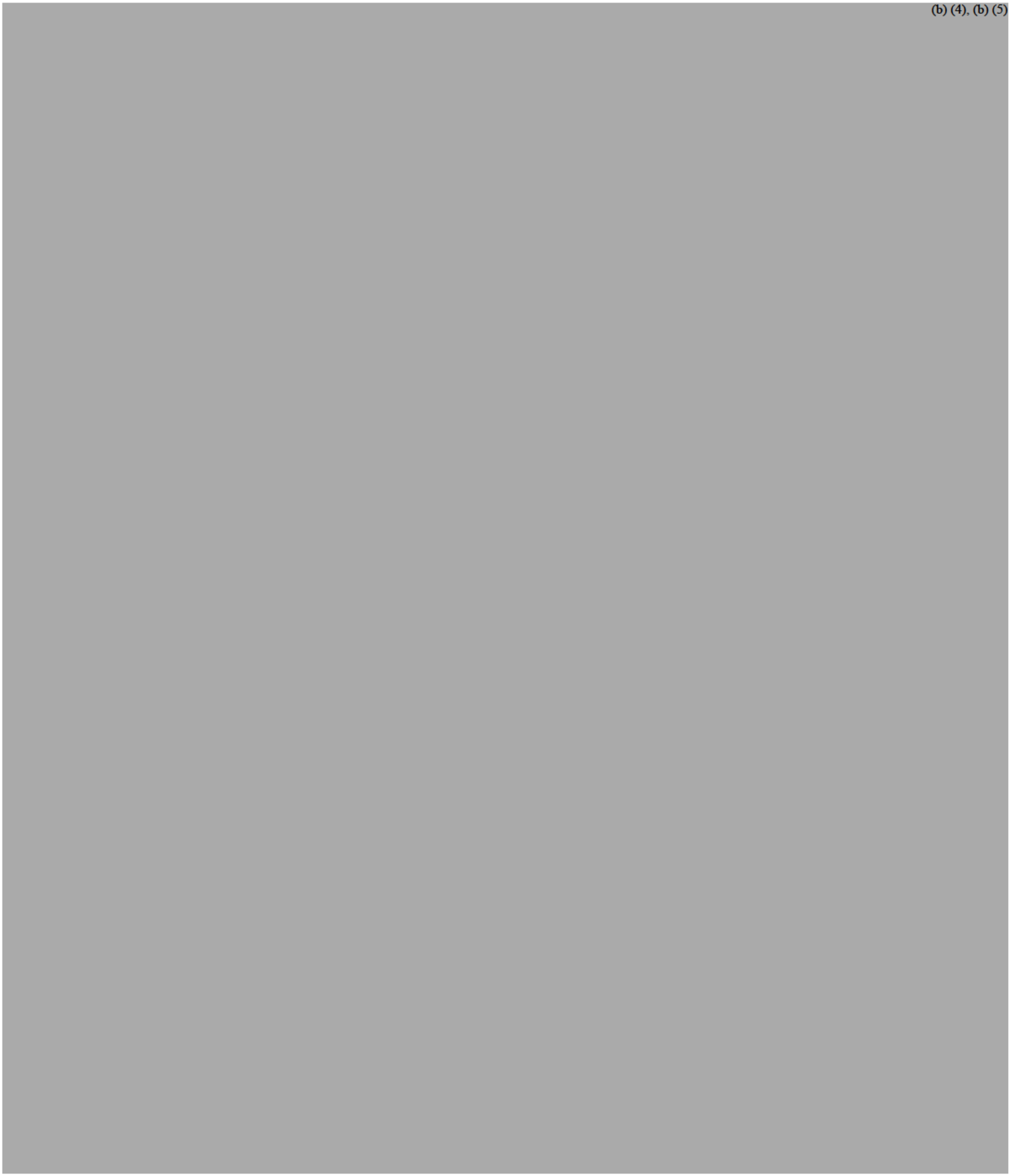
(b) (4), (b) (5)



(b) (4), (b) (5)







From: Wholley, David (FNIH) [T]
Sent: Tue, 17 Oct 2017 04:28:35 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Baker, Rebecca (NIH/OD) [E];Porter, Linda (NIH/NINDS) [E];Menetski, Joseph (FNIH) [T];Biarnes, Michael (FNIH) [T];Melencio, Cheryl (FNIH) [T]
Subject: email drafts for opioids partnership
Attachments: Opioid_FC email to Ind CoChair_101617dw.docx, Opioids email to partner reps_10-16-17.docx, Opioids FC email to FA2 academics with NIH history_10-16-17.docx, Opioids FC email to FA2 academics_10-16-17.docx

Francis,
Here are the emails I have composed for

1. (b) (5) the lead industry co-chair identified by Walter and Linda for Focus Area #2. Note that we are still waiting to see if Nora wants an industry co-chair for area #1.
2. Invitation to all industry reps to participate in the partnership generally and the Friday call specifically. Note you may need to adjust how logistics info for the call is handled—I think we will need Rebecca's help here. The note would be sent to the attendees on the lists provided to Rebecca by Bill Chin.
3. An invitation to academic invitees to work on focus area #2 who attended one of the NIH workshops over the summer. Again, we would need to see Nora's plan and whether she wants such invitees for focus area 1 before proceeding.
4. An invitation to academic invitees to work on focus area #2 who did NOT attend any of the NIH workshops and are newer to the process.

The academic invitees for notes 3 and 4 are:

(b) (5)

We are working to find their email addresses, but I am copying Linda Porter to see if she can provide them faster. Linda, I assume Francis should start with (b) (5) DeBar, and then based on the outcome of Friday's call we can invite (b) (5) (b) (5)

Thanks, David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

(b) (5)

(b) (5)

(b) (5)

(b) (5)

(b) (5)

From: Wholley, David (FNIH) [T]
Sent: Mon, 20 Nov 2017 14:45:38 +0000
To: Collins, Francis (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Koroshetz, Walter (NIH/NINDS) [E];Volkow, Nora (NIH/NIDA) [E];Baker, Rebecca (NIH/OD) [E];Wolinetz, Carrie (NIH/OD) [E]
Subject: FDA Meeting conflict

All – on this morning's Opioids Biomarker Working Group call Sharon Hertz informed the group that FDA has a meeting on December 11 and 12 to discuss packaging configurations that can reduce risk, and rather publicly suggested that our planned Dec 12-13 meeting would therefore propose a conflict that could be problematic for 'many participants.' Is this the meeting that Nora mentioned in some of our earlier Thursday calls, or something new (she says it is in the FR)? And how should we handle this? We are pretty set for the 12th and 13th and moving the date may be even more problematic for our efforts. I will need to respond to Sharon in any event. Please advise.

Thanks, David

We've moved! Please find our new address below.
David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852
*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Wholley, David (FNIH) [T]
Sent: Thu, 21 Dec 2017 17:12:34 +0000
To: Chin, Bill (Chin@phrma.org)
Cc: Collins, Francis (NIH/OD) [E];Baker, Rebecca (NIH/OD) [E]
Subject: FNIH PPP Update for BMAC final draft 12-20-17
Attachments: FNIH PPP Update for BMAC final draft 12-20-17.docx

Bill – sorry for the slight delay, had some computer trouble at the time I needed it least, but all resolved. Please see the progress summary you requested for the BMAC of the opioid partnership, which has been reviewed by our NIH colleagues. It may be a bit longer than you wanted, but I preserved your opening and closing sections from your earlier document (governance modified to fit our discussions at the face to face) which take up about page in themselves.

I have also included the additional updates you requested on PACT and AMP. These should be easy to shorten if you need to as you can pretty much drop the bullets and partner lists from each section if desired.

Hope this works for you. Please let me know anything else you may need.

David

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

From: Wholley, David (FNIH) [T]
Sent: Fri, 29 Sep 2017 00:48:28 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Baker, Rebecca (NIH/OD) [E];Wolinetz, Carrie (NIH/OD) [E];Adam, Stacey (FNIH) [T];Melencio, Cheryl (FNIH) [T]
Subject: FW:
Attachments: Updated PACT Executive Summary 092617.docx

Francis, Rebecca:

Below is the sample email, with attachment, that I showed you at our meeting today and that I drafted for Francis to send (b) (4) (b) (4) (b) (4) Please let me know if you need email addresses for any of these. Thanks, David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Wholley, David (FNIH) [T]
Sent: Thursday, September 28, 2017 11:18 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: FW:

Dear Roger:

I wanted to give you an update on the Partnership for Accelerating Cancer Therapies (PACT). As you may recall NIH worked with FNIH, FDA, and 14 pharmaceutical companies (b) (4) earlier this year to plan a public-private partnership that would help coordinate the development of standardized biomarkers and assays needed to conduct trials of new cancer immunotherapies and combination therapies. The resulting plan builds on a $160 million investment by NCI over 5 years in core laboratory and database infrastructure with (b) (4) to expand the number of novel markers, assays, and types of data that can be developed.

(b) (4)

(b) (4) As a result, we now have X companies pledged to support PACT, and will be holding an announcement at the National Press Club here in Washington on October 12 with all of the participants, hosted by Secretary Price.

(b) (4) Do you might be able to reconsider joining PACT given where things now stand? It would be great to know before the 12th so we can include you in the planning for the announcement.

(b) (4)

Regards,
Francis

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

(b) (4), (b) (5)

(b) (4), (b) (5)

From: Wholley, David (FNIH) [T]
Sent: Tue, 12 Dec 2017 11:11:19 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: Fw: AMP Extended EC 12-15-2017 2nd DRAFT.pptx

Just got this--think we are on the same track.
Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E] (b) (6)
Sent: Tuesday, December 12, 2017 5:18 AM
To: Wholley, David (FNIH) [T]
Cc: Gadbois, Ellen (NIH/OD) [E]; Singh, Jyoti (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]; Morgan, Emily (FNIH) [T]
Subject: RE: AMP Extended EC 12-15-2017 2nd DRAFT.pptx

Before deleting slides 37 and 38, please consult with Bob Carter – and offer him the chance to make a different cut if these are somehow really important to him.

FC

From: Wholley, David (FNIH) [T]
Sent: Monday, December 11, 2017 9:40 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Gadbois, Ellen (NIH/OD) [E] (b) (6)>; Singh, Jyoti (NIH/OD) [E] (b) (6); Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Morgan, Emily (FNIH) [T] <emorgan@fnih.org>
Subject: Re: AMP Extended EC 12-15-2017 2nd DRAFT.pptx

PS, yes please reach out to Mikael. Cheryl or Emily can you please make the deletions Francis has suggested and resend him the deck to use with Mikael? Thanks

Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Monday, December 11, 2017 9:33 PM
To: Wholley, David (FNIH) [T]
Cc: Gadbois, Ellen (NIH/OD) [E]; Singh, Jyoti (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]
Subject: RE: AMP Extended EC 12-15-2017 2nd DRAFT.pptx

Hi David,

Wow, this is better but still seems overly detailed. With 66 slides I fear it will be hard to preserve much time for discussion in our 90 minute call.

Not including the title slides, I count 12 slides for T2D, 21 for RA/SLE, and 15 for AD. That makes me worry most about RA/SLE. I don't see how the team can present 21 data slides in 15 minutes without frustrating the listeners. Can you ask Bob Carter to consider this one more time, and potentially drop a few slides that are not essential? Slides 37 and 38 look like candidates for deletion to me.

Remembering a prior EEC where the introductory remarks from Mikael were elegant and inspiring, but went on WAY too long, shall I reach out to him to divide up that part, and emphasize that the introductory remarks should be very brief? In that regard, I'd recommend dropping slide 7 – it has a lot of details, and Lon and Patrick are no longer involved. Can be referred to verbally.

FC

From: Wholley, David (FNIH) [T]
Sent: Monday, December 11, 2017 4:25 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Gadbois, Ellen (NIH/OD) [E] (b) (6); Singh, Jyoti (NIH/OD) [E] (b) (6)>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>
Subject: AMP Extended EC 12-15-2017 2nd DRAFT.pptx

Hi Francis – As requested, here is the second pass at the slides for the AMP EEC this Friday. We've done our best to work with the co-chairs to prune and improve the slides per your feedback on last week's pre-call. Let us know what you think, including where you think there are any additional opportunities for condensing this. Thanks, David

From: Wholley, David (FNIH) [T]
Sent: Sun, 20 Aug 2017 15:50:34 +0000
To: Koroshetz, Walter (NIH/NINDS) [E];Collins, Francis (NIH/OD) [E]
Cc: Sutherland, Margaret (NIH/NINDS) [E];Tabak, Lawrence (NIH/OD) [E];Canet-Aviles, Rosa (FNIH) [T];Gadbois, Ellen (NIH/OD) [E]
Subject: FW: AMP Parkinson's Disease proposal

Francis and Walter:

See below for some great news. I had a call with Rupert Vessey of Celgene about three weeks ago to confirm their participation in the Partnership for Advancing Cancer Therapies (PACT), and used the occasion to talk about all the progress we are making on AMP and in particular the launch of our Parkinson's disease initiative. Rupert said Celgene has recently become more interested in PD, so I sent him the plan and current status. We will move forward immediately to integrate them into the launch process.

This comes at a fortunate time because of GSK's announcement earlier this month that they are withdrawing from neuroscience (as part of a broader strategy to focus their research portfolio on a few key areas and cut some 30 development programs) We continue to take the approach of acting as if their previous commitment will stand—sending them the final research plan and funding agreement, etc—but we have not heard from our chief PD contact, Min Li, since April, and I think the odds are against their continuing.

We are continuing to follow some additional leads (b) (4)

David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Rupert Vessey [mailto:rvessey@celgene.com]
Sent: Saturday, August 19, 2017 10:10 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnih.org>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Richard Hargreaves <rihargreaves@celgene.com>; Michael Carulli <mcarulli@celgene.com>; Scott Bateman <SBateman@celgene.com>
Subject: RE: AMP Parkinson's Disease proposal

David
We have reviewed the AMP for PD and would like to join the group (b) (4) Richard Hargreaves is our neuro leader and we will assign someone to be our representative. Mike Carulli leads

our business operations and Scott Bateman handles our collaboration and they can help with the administrative issues.
Rupert

From: Wholley, David (FNIH) [T] [mailto:dwholley@fnih.org]
Sent: Friday, July 28, 2017 8:03 PM
To: Rupert Vessey <rvessey@celgene.com>
Cc: Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnih.org>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>
Subject: AMP Parkinson's Disease proposal
Importance: High

Dear Rupert,

Thanks for taking the time to speak with us about PACT today. As you requested, here is the additional background and proposal information on the pending AMP Parkinson's disease (AMP PD) initiative. Over the last 8-12 months we took this through the same planning process as for the other AMP initiatives: a white paper generated by a broader group of NIH, industry, and academic partners, followed by a more detailed research plan (in this case, near-final) drafted by NIH and the interested private sector partners alone (so academics can apply to NIH grants without incurring any conflicts of interest). The current status is that we are ready to finalize the project plan in the next 30-45 days (NINDS has some FY 2017 funds they need to disburse to the project before the end of September) and are working with a current projected budget over five years currently totaling $20 million over five years: $10 million over 5 years to be contributed by NIH, and commitments (b) (4) through FNIH) from each of five private sector partners: GSK, the Michael J. Fox Foundation, Pfizer, Sanofi, and Verily. (Verily is providing the software and analytic infrastructure for the resulting data platform; (b) (4)

Just as a bit of additional history: the original white paper plan considered a broader scope that included two distinct projects: 1) Target and Assays, which would identify and validate putative new therapeutic targets for PD based on genetics, and 2) Clinical Biomarkers to enable Proof-of-Concept (POC) Trials, which would focus on testing clinical biomarkers to be used in phase 2 POC trials. After thorough review by all partners, a decision was made to move forward, at present, with "Project 2" only for AMP PD, as the arm that is more affordable and pragmatically proximal to industry development needs. We are still seeking non-industry funds to see if we can get program #1 funded.

The current plan takes advantage of already existing exceptional, clinically phenotyped, longitudinal genetically characterized PD cohorts with extensive, state-of-the-art linked longitudinal biobanks (PPMI, PDBP, Harvard Biomarkers Study, PARS, and others) and encompasses deep molecular characterization, neuroimaging and multimodal imaging, and profiling of PD patients. The plan includes providing open data access and sharing to dissect

new targets, dissect disease subtypes, markers tracking progression, and markers that predict progression. Additionally, AMP PD is designed to provide an interface for data access and analysis for AMP PD investigators and the larger research community which we are calling the AMP-PD Knowledge Platform.

Standardized data analysis pipelines will be developed for WGS, RNA seq, epigenomics, and proteomics data types regardless of the AMP-PD platform used. Based on our recent face to face planning meeting, the group has identified several platforms that meet the criteria of high-throughput, precision, and genome-scale resolution and which are being considered for prioritization. I've attached the latest draft of the current research plan that provides further detail. (Although the draft is marked confidential, please feel free to circulate within Celgene.)

[redacted] (b) (4) to supplement/expand the existing plan; while the group has a fairly good idea of where the buy-ups would be by now, Celgene would of course have a voice in determining the disposition of the funds through the joint NIH/industry Steering Committee we are setting up. We'd also report out to you personally twice a year on progress through the Extended Executive Committee teleconferences we host with all of the industry and non-profit R&D heads.

If you or any of your staff are interested in discussing further, my assistant, Cheryl Melencio, and the Scientific Program Manager responsible for this effort, Rosa Canet-Aviles, can set up a call quickly to discuss the effort, and can include colleagues from NINDS and MJFF as needed.

Please let me know how you'd like to proceed.
Regards,
David Wholley

****
THIS ELECTRONIC MAIL MESSAGE AND ANY ATTACHMENT IS
CONFIDENTIAL AND MAY CONTAIN LEGALLY PRIVILEGED
INFORMATION INTENDED ONLY FOR THE USE OF THE INDIVIDUAL
OR INDIVIDUALS NAMED ABOVE.
If the reader is not the intended recipient, or the
employee or agent responsible to deliver it to the
intended recipient, you are hereby notified that any
dissemination, distribution or copying of this
communication is strictly prohibited. If you have
received this communication in error, please reply to the
sender to notify us of the error and delete the original
message. Thank You.

From: Wholley, David (FNIH) [T]
Sent: Thu, 24 Aug 2017 14:41:15 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Hoffmann, Steve (FNIH) [T]
Subject: FW: AMP RA/SLE Validation - Response to Dr. Collins
Importance: High

(b) (5)

[redacted]

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Hoffmann, Steve (FNIH) [T]
Sent: Tuesday, August 22, 2017 1:54 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Vardanian, Lilit (FNIH) [T] <lvardanian@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnih.org>
Subject: RE: AMP RA/SLE Validation - Response to Dr. Collins
Importance: High

David,

(b) (5)

[redacted]

(b) (5)

Kind regards,

Steve

From: Wholley, David (FNIH) [T]
Sent: Fri, 7 Jul 2017 12:21:45 -0400
To: Koroshetz, Walter (NIH/NINDS) [E];Sutherland, Margaret (NIH/NINDS) [E];tsherer
Cc: Collins, Francis (NIH/OD) [E];Canet-Aviles, Rosa (FNIH) [T]
Subject: FW: Any feedback you can give me from yesterday's meeting

FYI. Sounds like they are moving this forward.

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: William Marks [mailto (b) (6)
Sent: Friday, July 07, 2017 11:56 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnih.org>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; David Glazer (b) (6); Ritu Kapur (b) (6)
Subject: RE: Any feedback you can give me from yesterday's meeting

Thanks for your message, David.

We have already been in discussions with MJFF to collaborate on PPMI by providing some of our sensors for that cohort.

We met with Andy yesterday and are working on a plan internally. We will be back in touch soon.

I can be your point of contact from Verily if there are any questions in the meantime.

Thanks,
Bill

On Jul 7, 2017 8:45 AM, "Wholley, David (FNIH) [T]" <dwholley@fnih.org> wrote:
Hi Bill:
As you may have heard, Francis Collins spoke with Andy Conrad this past Monday about this issue, and from what I heard Andy was as a result much more in favor of Verily supporting AMP PD. He also told Francis he would be very interested in funding the addition of wearable devices to the AMP research agenda. I have followed up on this with NINDS and the Michael J. Fox Foundation, and can confirm that

there would indeed be interest in seeing if we can take Andy up on his offer and proactively create some type of partnership that would test the feasibility and utility of wearable devices in longitudinal studies using the PPMI study population, while continuing to pursue vigorously the existing original AMP PD research plan. I don't know how this should best be handled internally at Verily—whether we need to approach Andy directly or work through you and others to discuss this first. In any event if you will let me know who from Verily should be involved my office (Cheryl Melencio) can set up a call with you all and Todd Sherer, Marg Sutherland, and Walter Koroshetz as a first step to moving forward on this. Please let me know. Thanks, David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Wholley, David (FNIH) [T]
Sent: Tue, 10 Oct 2017 13:54:48 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Baker, Rebecca (NIH/OD) [E]
Subject: FW: BMS is in

Hi, Francis – sorry to bother you, but I got a call this morning from a Daniel Levine at BMS who is in R&D ops and is trying to track down what is going on with PACT. I have the email regarding your phone conversation with Tom Lynch, but would you happen to have received any communication in writing from Tom Lynch regarding their decision to join PACT? Not a big deal, but might be helpful to Dan if you could pass along anything to me that floats up on an email search. Thanks, David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Collins, Francis (NIH/OD) [E]
Sent: Friday, July 28, 2017 7:41 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Wood, Gretchen (NIH/OD) [E] (b) (6) Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Adam, Stacey (FNIH) [T] <sadam@fnih.org>; Lowy, Douglas (NIH/NCI) [E] (b) (6); Doroshow, James (NIH/NCI) [E] (b) (6) Tabak, Lawrence (NIH/OD) [E] (b) (6)
Subject: BMS is in

Just spoke with Tom Lynch of BMS. His concerns were two fold: 1) BMS didn't want to be the only company, or just one of two or three, to sign on; 2) the $10M price tag was awfully steep. Hearing that we have 4 sign ons (and probably 6), and that the price tag is now $5M, he said "count us in!". No equivocation. Done.

He was particularly glad to hear that FDA will be involved, as he thinks there is a great opportunity for precompetitive sharing of biomarker information.

FC

From: Wholley, David (FNIH) [T]
Sent: Wed, 5 Jul 2017 18:34:27 -0400
To: Collins, Francis (NIH/OD) [E];Lowy, Douglas (NIH/NCI) [E];Tabak, Lawrence (NIH/OD) [E];Doroshow, James (NIH/NCI) [E]
Cc: Lubenow, Anne (NIH/NCI) [E];Baker, Rebecca (NIH/OD) [E];Adam, Stacey (FNIH) [T]
Subject: (b) (4)

This is their second "no" and therefore definitive. Will keep you posted as I hear from others.

Sent from my BlackBerry 10 smartphone.

From: Wholley, David (FNIH) [T]
Sent: Mon, 11 Dec 2017 21:25:16 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Gadbois, Ellen (NIH/OD) [E];Singh, Jyoti (NIH/OD) [E];Melencio, Cheryl (FNIH) [T]
Subject: AMP Extended EC 12-15-2017 2nd DRAFT.pptx
Attachments: AMP Extended EC 12-15-2017 2nd DRAFT.pptx

Hi Francis – As requested, here is the second pass at the slides for the AMP EEC this Friday. We've done our best to work with the co-chairs to prune and improve the slides per your feedback on last week's pre-call. Let us know what you think, including where you think there are any additional opportunities for condensing this. Thanks, David

Accelerating Medicines PartnershipExtended Executive Committee Update #7

15 December 2017



FNIH
Foundation for the National Institutes of Health

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

Accelerating Medicines PartnershipType 2 Diabetes

(b) (4)

NIDDKMelissa Thomas,

(b) (4)



FNIH
Foundation for the National Institutes of Health

NIH - 001

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

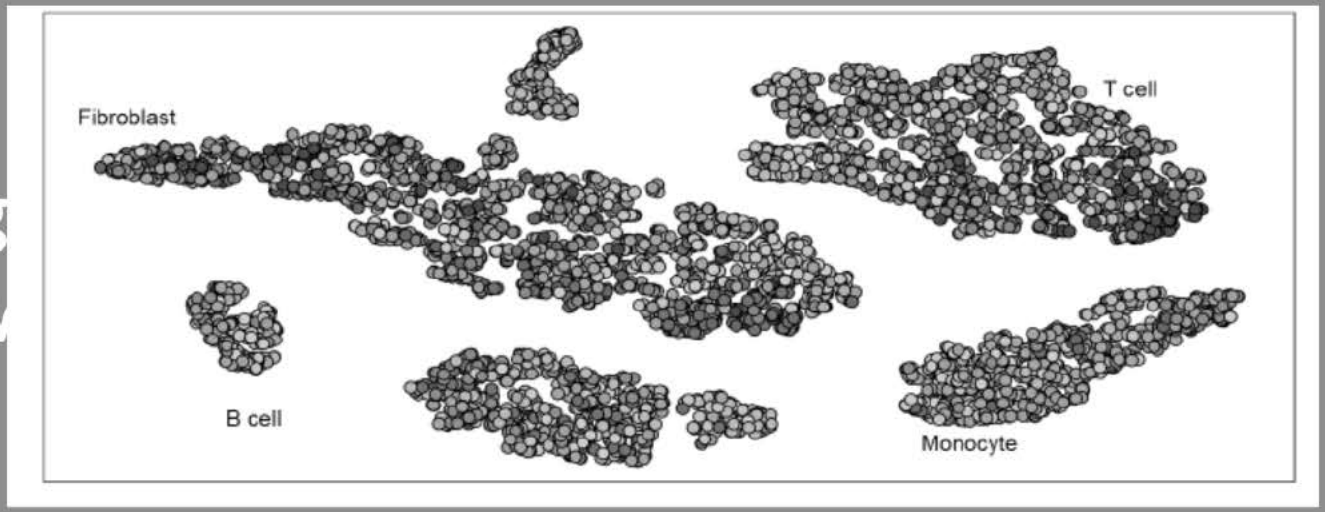
(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

Accelerating
Carter, NIAM



FNIH

Foundation for the
National Institutes of Health

NIH - 001706



(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

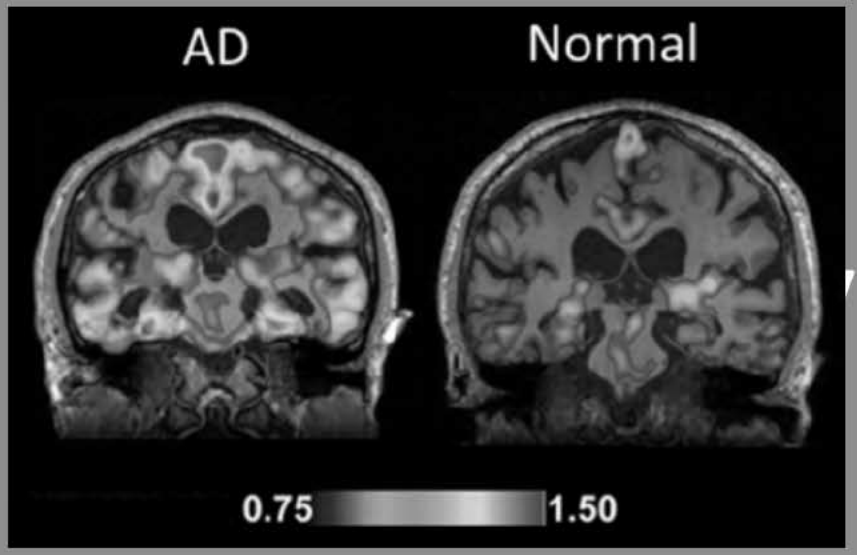
(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

Accelerating Medicines Disease Laurie Ryan,



FNIH

Foundation for the National Institutes of Health

NIH - 001727



(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

Accelerating Medicines PartnershipParkinson's DiseaseProgram Development

(b) (4)

(b) (4) Marg Sutherland, NINDS

FNIH

Foundation for the National Institutes of Health

NIH - 001742



(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

Extended Executive Committee

- **Next Meeting:AMP Extended Executive Committee: June 29**

Backup Slides

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

From: Wholley, David (FNIH) [T]
Sent: Fri, 25 Aug 2017 12:13:57 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Tabak, Lawrence (NIH/OD) [E]
Subject: Apologies

Sorry about my brain glitch. Not typical of me. Hope you thought the call went well nevertheless.

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Wholley, David (FNIH) [T]
Sent: Tue, 7 Nov 2017 23:21:32 +0000
To: Flores, Christopher [CONUS]
Cc: Collins, Francis (NIH/OD) [E];Chin, Bill (Chin@phrma.org);Baker, Rebecca (NIH/OD) [E];Biarnes, Michael (FNIH) [T]
Subject: Asset Repurposing/Development for Pain

Dear Chris –
Thank you again for taking the time this afternoon to share with me your concerns about the pain medication development portion of the opioid partnership. As promised, I have discussed this further with both Francis Collins and Bill Chin, and we agree that finding a way to incorporate the offer of specific assets—chemical, technology, data or otherwise—from companies into the partnership is distinct from "data sharing" as described in the plan and represents a near-term opportunity we need to figure out how to take advantage of. Rather than run this as part of the larger workstreams, we are wondering if perhaps a better approach might not be to get together a smaller group of companies with assets to offer in the pain space for a focused discussion to figure out how best to move this forward on a fast track. We'd involve folks from NINDS and NCATS on the NIH side, and thought we could start with you and perhaps Ken Verburg among the company representatives. Would you be amenable to that approach, and if so are there a few other company folks you think we should invite? Please let me know.
Thanks,
David

We've moved! Please find our new address below.
David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852
*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Wholley, David (FNIH) [T]
Sent: Mon, 13 Nov 2017 02:51:12 +0000
To: Flores, Christopher [CONUS];Austin, Christopher (NIH/NCATS) [E];Kenneth.m.verburg@pfizer.com;min.x.li@gsk.com;john.dunlop@amgen.com;Colvis, Christine (NIH/NCATS) [E];Chin, Bill (Chin@phrma.org);Koroshetz, Walter (NIH/NINDS) [E]
Cc: Volkow, Nora (NIH/NIDA) [E];Stein, Jack (NIH/NIDA) [E];Wright, Clinton (NIH/NINDS) [E];Mark Mintun;Thomas, David (NIH/NIDA) [E];Oshinsky, Michael (NIH/NINDS) [E];Biarnes, Michael (FNIH) [T];Melencio, Cheryl (FNIH) [T];Collins, Francis (NIH/OD) [E];Baker, Rebecca (NIH/OD) [E];Porter, Linda (NIH/NINDS) [E]
Subject: Asset Repurposing Group for Opioids Partnership

Dear colleagues:

As you know we have been pushing forward on specific plans for an opioids partnership to accelerate new treatments for OUD, overdose, and pain. In the pain focus area, FNIH has already formed three Working Groups—in data sharing, biomarkers, and clinical trials networks and design—with a broad array of stakeholders, and NIDA is engaging a number of companies to explore new formulations and combinations of therapies to address overdose and OUD. It has come to our attention, however, that there may be opportunities to share specific chemical assets, technologies and related datasets that are not adequately covered by the existing working group arrangements, particularly in pain. After conferring with the leadership of the partnership we've decided to convene a focused team to consider these opportunities and how best to address them. Chris Flores of Johnson & Johnson and Chris Austin of NCATS will lead this discussion.

I am asking the addressees on this note to form the core of this group and also ask if we can set aside 60 minutes or so for an initial call sometime in the next week or two to discuss what assets may be available and how best to approach a plan for deploying them in support of the partnership. To provide a broader view (and ensure continuity with other efforts) I am also inviting Nora Volkow and Jack Stein from NIDA and the co-chairs of the three pain Working Groups to join the conversation if they can. Can you please respond to Cheryl Melencio on our staff, who will be sending out a poll shortly for this call?

I look forward to our discussion.

Regards,
David Wholley

We've moved! Please find our new address below.
David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852
*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Wholley, David (FNIH) [T]
Sent: Tue, 12 Dec 2017 02:33:18 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: Automatic reply: AMP Extended EC 12-15-2017 2nd DRAFT.pptx

I will be helping to manage a scientific meeting all day on December 12 and 13 and will have limited ability to respond to other matters. Best way to reach me if urgent is via email.

From: Wholley, David (FNIH) [T]
Sent: Sun, 27 Aug 2017 13:24:13 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: Automatic reply: Apologies

I am out of the office on annual leave until Tuesday, September 5. For urgent matters please call or email Cheryl Melencio (cmelencio@fnih.org or 301-402-4970).

From: Wholley, David (FNIH) [T]
Sent: Mon, 16 Oct 2017 14:14:34 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: Automatic reply: can you call in at noon?

I am out of the office on annual leave until Tuesday, September 5. For urgent matters please call or email Cheryl Melencio (cmelencio@fnih.org or 301-402-4970).

From: Wholley, David (FNIH) [T]
Sent: Sat, 1 Jul 2017 11:59:11 -0400
To: Collins, Francis (NIH/OD) [E]
Subject: Automatic reply: Companies and PACT

I am out of the office as our offices are closed for the holidays until Wednesday July 5.

From: Wholley, David (FNIH) [T]
Sent: Mon, 17 Jul 2017 07:02:50 -0400
To: Collins, Francis (NIH/OD) [E]
Subject: Automatic reply: meeting tomorrow morning

I am out of the office on vacation until Monday July 24. For urgent matters please call or email Emily Morgan (emorgan@fnih.org or 301-435-9220.

From: Wholley, David (FNIH) [T]
Sent: Fri, 3 Nov 2017 14:26:55 +0000
To: Collins, Francis (NIH/OD) [E];Koroshetz, Walter (NIH/NINDS) [E];Tabak, Lawrence (NIH/OD) [E];Volkow, Nora (NIH/NIDA) [E]
Cc: Porter, Linda (NIH/NINDS) [E];Baker, Rebecca (NIH/OD) [E];Wolinetz, Carrie (NIH/OD) [E];Stein, Jack (NIH/NIDA) [E];Biarnes, Michael (FNIH) [T];Menetski, Joseph (FNIH) [T];Melencio, Cheryl (FNIH) [T];McManus, Ayanna (NIH/OD) [E]
Subject: Availability week of December 11 for Opioids face to face meeting

Dear All—
Since our meeting yesterday our FNIH Events group has identified several possible venues for a 2-day face to face meeting on opioids. I recall from yesterday that several of you mentioned you had some conflicts or previous engagements that week. In the interest of nailing down a venue (which get filled fast this time of year) and the meeting dates, can you please advise us immediately as to your preferred 2-day slot that week? I would imagine that given the emphasis on pain the schedules for Francis, Walter, and Linda would be particularly critical. A reply today would be greatly appreciated.
Thanks,
David

We've moved! Please find our new address below.
David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852
*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Wholley, David (FNIH) [T]
Sent: Wed, 20 Dec 2017 20:56:08 +0000
To: Koroshetz, Walter (NIH/NINDS) [E]
Cc: Baker, Rebecca (NIH/OD) [E];Porter, Linda (NIH/NINDS) [E];Porter, Linda (NIH/NINDS) [E];Volkow, Nora (NIH/NIDA) [E];Stein, Jack (NIH/NIDA) [E];Collins, Francis (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Wolinetz, Carrie (NIH/OD) [E];Biarnes, Michael (FNIH) [T];Menetski, Joseph (FNIH) [T]
Subject: FW: FAST TURNAROUND REVIEW: Opioid PPP update for BMAC 12-19-17 draft for NIH
Attachments: Opioid PPP update for BMAC 12-19-17 draft rb2 fsc.docx

Walter,
Thanks for taking the time to review this and make changes. I think your changes on page 2 to reorder and tighten up the Asset and Data Section and Biomarkers and Endpoints are really very helpful. My only concern would be your edits to the "Strategic Research Goals" up front— this is copied pretty closely from the last document sent to PhRMA, and I would be concerned that changing too much of the language there makes it look like we are "moving the goalposts." I would rather we kept that section as is and address the changes needed in the Progress Update section.

Since Nora and Larry sent their changes in a separate document I will address those in a separate email. Thanks, David

---

From: Koroshetz, Walter (NIH/NINDS) [E]
Sent: Wednesday, December 20, 2017 12:41 PM
To: Baker, Rebecca (NIH/OD) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6)
Cc: Collins, Francis (NIH/OD) [E] (b) (6)>; Wolinetz, Carrie (NIH/OD) [E] (b) (6) Tabak, Lawrence (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>
Subject: RE: FAST TURNAROUND REVIEW: Opioid PPP update for BMAC 12-19-17 draft for NIH

Thanks Rebecca. I took a quick look and added edits. If doesn't go out tonight let me know and I can relook. Booked solid til 9PM.

Walter

From: Baker, Rebecca (NIH/OD) [E]
Sent: Wednesday, December 20, 2017 8:39 AM
To: Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6) Volkow, Nora (NIH/NIDA) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6)
Cc: Collins, Francis (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6)>; Tabak, Lawrence (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>
Subject: FAST TURNAROUND REVIEW: Opioid PPP update for BMAC 12-19-17 draft for NIH

Good morning,

As follow up to last week's partnership design meeting, FNIH has drafted the attached summary to share with the PhRMA Biomedical Advisory Council.

PhRMA has asked for a draft by COB today. Could you please review and send your revisions and edits by 4 PM today? Please be sure to copy David and Mike.

Thank in advance for your thoughts,

Rebecca

From: Wholley, David (FNIH) [T]
Sent: Tuesday, December 19, 2017 7:38 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Baker, Rebecca (NIH/OD) [E] (b) (6); Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>
Subject: Opioid PPP update for BMAC 12-19-17 draft for NIH

Francis – Please see my draft of the summary of our progress on the opioid initiative that Bill Chin requested in advance of the January 4 BMAC meeting. He asked for two pages; however given his introductory and closing sections are a page long in themselves my draft result is three pages, but does let them know we've come up with specific conclusions. Feel free to suggest changes to shorten it further of course. I have yet to add the page summarizing AMP and PACT that he requested as this took most of the effort.

(b) (4)

Rebecca, I leave to you whether you think we should simply distribute this more broadly at this point (to Nora, Jack, Walter, etc) or whether you think Francis will want to/have time to make changes first. Bill asked for a final draft by cob tomorrow.

Thanks, David

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

From: Wholley, David (FNIH) [T]
Sent: Mon, 27 Nov 2017 16:52:42 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Volkow, Nora (NIH/NIDA) [E];Koroshetz, Walter (NIH/NINDS) [E];Stein, Jack (NIH/NIDA) [E];Wolinetz, Carrie (NIH/OD) [E];Porter, Linda (NIH/NINDS) [E];Tabak, Lawrence (NIH/OD) [E];Baker, Rebecca (NIH/OD) [E];Biarnes, Michael (FNIH) [T];Menetski, Joseph (FNIH) [T]
Subject: FW: FDA Meeting on December 11-12

Please see below. I think we stick to our original plan of kicking this off with focus area 1 on the morning of day 1 (12th), then going to pain on that afternoon of day 1 and continuing the discussion the following day (13th). We can include the key conclusions from focus area 1 discussion in the sum-up at the end of day 2 (of course). Let me know what you think.

From: Hertz, Sharon H (b) (6)
Sent: Monday, November 27, 2017 11:30 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: RE: FDA Meeting on December 11-12

Thanks, that is a great idea except Ellen will be covering the division while I am at the FDA meeting. I understand that it is difficult to move meetings with so many people.

I don't think you need to change the agenda for the meeting. Both areas are important, so I'll just have to miss whichever is on the 12th.

Sharon

Sharon Hertz, MD
Division Director
DAAAP
(b) (6)

From: Wholley, David (FNIH) [T] [mailto:dwholley@fnih.org]
Sent: Monday, November 27, 2017 11:18 AM
To: Hertz, Sharon H (b) (6)
Cc: Biarnes, Michael C (NIH) <mbiarnes@fnih.org>; Menetski, Joseph M (NIH) <jmenetski@fnih.org>
Subject: RE: FDA Meeting on December 11-12

What if we did pain on the 12th and delayed focus area 1 (addiction and overdose) discussions to the morning of day 2 (the 13th). Am assuming someone like Ellen Fields might be able to make both the 12th and 13th, and provide some continuity. Would that work?

From: Hertz, Sharon H (b) (6)
Sent: Monday, November 27, 2017 9:17 AM

To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: RE: FDA Meeting on December 11-12

It is some of the companies. I don't know if it is the same people or not, but there are many issues that could impact the drug and device companies so we expect many to attend. Beyond that, many of us at FDA are conflicted. For example, Doug Throckmorton and I are speaking/moderating on the 12th. We can have people cover, but I'm sure you understand that it is very difficult to have continuity from us if different people attend meetings on the same topic.

Sharon

Sharon Hertz, MD
Division Director
DAAAP
(b) (6)

From: Wholley, David (FNIH) [T] [mailto:dwholley@fnih.org]
Sent: Sunday, November 26, 2017 1:09 PM
To: Hertz, Sharon H (b) (6)
Cc: Biarnes, Michael C (NIH) <mbiarnes@fnih.org>; Menetski, Joseph M (NIH) <jmenetski@fnih.org>
Subject: FDA Meeting on December 11-12

Hi Sharon—
On one of our opioid partnership calls last week you brought up a concern that our face to face meeting scheduled for December 12-13 will conflict with a meeting FDA is planning to hold on Dec 11-12. I did speak to NIH leadership about this and they are concerned there are other conflicts, making moving the dates of the 12-13th meeting. In looking up the FDA meeting on the Federal Register, I notice it is specifically to discuss Packaging, Storing, and Disposal Options to Enhance Opioid Safety. Given this I am not sure of the degree of overlap with our planned meeting. I can see where some of the same companies would attend both meetings, but do you anticipate it will be the same actual personnel from those companies? And would the conflicts apply equally to the representatives and companies attending the current pain focus area discussions, or is it mainly a concern with respect to the companies associated with the addiction and overdose focus area currently led by NIDA? If the latter, though not optimal we could consider arranging the agenda for the 12-13 to put the addiction and overdose discussions on the second day. Please let me know. David

We've moved! Please find our new address below.
David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852
*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Wholley, David (FNIH) [T]
Sent: Tue, 18 Jul 2017 20:45:26 -0400
To: Collins, Francis (NIH/OD) [E];Koroshetz, Walter (NIH/NINDS) [E];Sutherland, Margaret (NIH/NINDS) [E]
Cc: Canet-Aviles, Rosa (FNIH) [T]
Subject: FW: Follow-Up on AMP PD

All:
Please see below. This is the best possible outcome I could have imagined. (b) (4) (b) (4) As Marg has pointed out the cloud computing services are really not all that significant in the scheme of things. I have asked Bill if Marg Sutherland can join the follow-up call, which Emily Morgan from our staff will coordinate. Onward.

Thanks,
David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: William Marks (b) (6)
Sent: Monday, July 17, 2017 10:10 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: David Glazer (b) (6); Ritu Kapur (b) (6); Thomas Snyder (b) (6)
Subject: Follow-Up on AMP PD

Dear David,

I'm writing to share some positive news with you.

We at Verily have had additional discussions, and out of these talks have emerged the following:

(b) (4)

(b) (4)

We'd like to arrange a phone call to discuss further. Might any of these dates/times work for you and your colleagues:

7/20: 11am-12noon Eastern Time
7/21: 11am-12noon or 5-6pm Eastern Time

Thanks--we're looking forward to discussing further.

Bill (for the Verily Team)

William J. Marks, Jr., MD, MS-HCM | 415-736-7580 | (b) (6)

Verily

From: Wholley, David (FNIH) [T]
Sent: Fri, 1 Dec 2017 14:03:20 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: FW: GSK representative at AMP Extended Executive Committee Meeting

fyi

From: Patrick Vallance [mailto:patrick.5.vallance@gsk.com]
Sent: Friday, December 1, 2017 8:51 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>; John Lepore <john.j.lepore@gsk.com>
Cc: Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>
Subject: RE: GSK representative at AMP Extended Executive Committee Meeting

David

Thanks for your note and congratulations. John Lepore will join for GSK and will provide the continuity

Best wishes

Patrick

Ps Not sure that the US has seen the last of me just yet!

From: Wholley, David (FNIH) [T] [mailto:dwholley@fnih.org]
Sent: 29 November 2017 21:55
To: Patrick Vallance <patrick.5.vallance@gsk.com>
Cc: Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>
Subject: GSK representative at AMP Extended Executive Committee Meeting

EXTERNAL

Dear Patrick:
First of all, congratulations on your new role in the UK beginning next year. You will be sorely missed over here.

I understand (in all senses of the term) you have declined the invitation to attend the AMP EEC call on December 15, and know that Lon Cardon has left GSK. Can you please suggest someone who should replace you and Lon on the EEC, or at least attend this call to represent GSK? Cheryl Melencio can follow up with a revised Outlook indication.

Thanks again, and best of luck
David Wholley

We've moved! Please find our new address below.
David Wholley

Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852
*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

GSK monitors email communications sent to and from GSK in order to protect GSK, our employees, customers, suppliers and business partners, from cyber threats and loss of GSK Information. GSK monitoring is conducted with appropriate confidentiality controls and in accordance with local laws and after appropriate consultation.

This e-mail was sent by GlaxoSmithKline Services Unlimited (registered in England and Wales No. 1047315), which is a member of the GlaxoSmithKline group of companies. The registered address of GlaxoSmithKline Services Unlimited is 980 Great West Road, Brentford, Middlesex TW8 9GS.

From: Wholley, David (FNIH) [T]
Sent: Fri, 8 Dec 2017 20:39:30 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Baker, Rebecca (NIH/OD) [E]
Subject: Fw: Can you co-lead the final meeting summary session next week with Francis Collins?

Sorry Francis--you bounced back on my latest email. Thanks, David
Sent from my BlackBerry 10 smartphone.

From: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Sent: Friday, December 8, 2017 3:34 PM
To: Chris Flores
Cc: Francis Collins; Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Baker, Rebecca (NIH/OD) [E]
Subject: Can you co-lead the final meeting summary session next week with Francis Collins?

Dear Chris,
In going over the final meeting agenda for next week's meeting on the opioids partnership with Francis Collins he asked if you might co-lead with him the final talk summarizing the major findings and action items of the two days on the afternoon of Dec. 13. We (FNIH) would summarize major points on powerpoint as we go along and have that available to you both after the final break to support your joint presentation and any ensuing discussion.Can you please let us know as soon as possible if you'd be willing to do this?
Thanks,
David Wholley
Sent from my BlackBerry 10 smartphone.

From: Wholley, David (FNIH) [T]
Sent: Fri, 25 Aug 2017 12:17:18 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Tabak, Lawrence (NIH/OD) [E]
Subject: FW: Conference call -

FYI, just received.

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Melencio, Cheryl (FNIH) [T]
Sent: Friday, August 25, 2017 8:06 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: Fwd: Conference call -

Fyi

Get Outlook for Android

From: Paul Stoffels (b) (6)
Sent: Friday, August 25, 2017 7:12:19 AM
To: Melencio, Cheryl (FNIH) [T]
Subject: Conference call -

Cheryl,

I'm caught up in a delay and will not be able to join at this moment. I'm really sorry.

Paul

Sent from my iPad

From: Wholley, David (FNIH) [T]
Sent: Fri, 29 Sep 2017 13:35:34 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Adam, Stacey (FNIH) [T];Baker, Rebecca (NIH/OD) [E];Wolinetz, Carrie (NIH/OD) [E]
Subject: FW: PACT and Novartis

Francis, fyi here is the response I sent to Engelman.

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Wholley, David (FNIH) [T]
Sent: Friday, September 29, 2017 9:08 AM
To: 'Engelman, Jeffrey' <jeffrey.engelman@novartis.com>
Cc: Caulfield, Anita <anita.caulfield@novartis.com>
Subject: RE: PACT and Novartis

Hi Jeff:

[redacted] (b) (4) It would be great if you could find a way to do the same, and join the group at the announcement on the 12th. Let me know if there is anything I can do to help that process.

David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Engelman, Jeffrey [mailto:jeffrey.engelman@novartis.com]
Sent: Thursday, September 28, 2017 9:20 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Caulfield, Anita <anita.caulfield@novartis.com>
Subject: Re: PACT and Novartis

Hi David,

I hope all is well. As you know, we are very supportive [redacted] (b) (4)

[redacted] (b) (4)

All the best,

Jeff

Jeffrey Engelman, M.D., Ph.D.
Global Head of Oncology
Novartis Institutes for BioMedical Research

Executive Assistant: Anita Caulfield
anita.caulfield@novartis.com
(617)-871-8200

From: "Wholley, David (FNIH) [T]" <dwholley@fnih.org>
Date: Tuesday, September 26, 2017 at 5:40 PM
To: Jeffrey Engelman <jeffrey.engelman@novartis.com>
Cc: "Caulfield, Anita" <anita.caulfield@novartis.com>
Subject: FW: PACT and Novartis

Hi Jeff:

The announcement of the launch of the Partnership to Advance Cancer Therapies (PACT) is almost certainly going to be on October 12, at the National Press Club. I am being asked by the NIH communications team whom to include in the announcement and related press push, etc. It would be great to have a formal decision from Novartis on PACT as soon as possible. (b) (4) (b) (4)

Thanks,

David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Bradner, James [mailto:james.bradner@novartis.com]
Sent: Tuesday, September 19, 2017 3:23 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: Re: PACT and Novartis

thank you, david. i know that jeff is meeting with (b) (4) this week to discuss. thanks so much - jay

--
Jay Bradner, M.D.
President | Novartis Institutes for BioMedical Research
james.bradner[at]novartis.com

From: "Wholley, David (FNIH) [T]" <dwholley@fnih.org>
Date: Monday, September 11, 2017 at 3:48 AM
To: James Bradner <james.bradner@novartis.com>, "Collins, Francis (NIH/OD) [E]" (b) (6)
Cc: "Jeff, Dana + Lexi Engelman" <jeffrey.engelman@novartis.com>, Scott Brown

<scott.brown@novartis.com>, Revathi Rammohan <revathi.rammohan@novartis.com>
Subject: Re: PACT and Novartis

Hi Jay,

(b) (4)

(b) (4) Please le us know if there are any questions remaining to be answered and we will be happy to jump on the phone.

Regards,
David Wholley
Foundation for the NIH
Sent from my BlackBerry 10 smartphone.

From: Bradner, James
Sent: Sunday, September 10, 2017 9:55 AM
To: Collins, Francis (NIH/OD) [E]
Cc: Wholley, David (FNIH) [T]; Engelman, Jeffrey; Brown, Scott; Rammohan, Revathi
Subject: Re: PACT and Novartis

Thank you, Francis. (b) (4)

(b) (4)

(b) (4) Best -

Jay

--
Jay Bradner, M.D.
President | Novartis Institutes for BioMedical Research
james.bradner[at]novartis.com

From: "Collins, Francis (NIH/OD) [E]" (b) (6)
Date: Saturday, September 9, 2017 at 5:08 PM
To: James Bradner <james.bradner@novartis.com>

Cc: "Wholley, David (FNIH) [T]" <dwholley@fnih.org>
Subject: PACT and Novartis

Hi Jay,

(b) (4)

Many thanks, Francis

From: Wholley, David (FNIH) [T]
Sent: Tue, 19 Sep 2017 13:10:01 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: FW: PACT and Novartis

(b) (4)

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Bradner, James [mailto:james.bradner@novartis.com]
Sent: Tuesday, September 19, 2017 3:23 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: Re: PACT and Novartis

thank you, david. i know that jeff is meeting with (b) (4) this week to discuss. thanks so much - jay

--
Jay Bradner, M.D.
President | Novartis Institutes for BioMedical Research
james.bradner[at]novartis.com

From: "Wholley, David (FNIH) [T]" <dwholley@fnih.org>
Date: Monday, September 11, 2017 at 3:48 AM
To: James Bradner <james.bradner@novartis.com>, "Collins, Francis (NIH/OD) [E]"
(b) (6)
Cc: "Jeff, Dana + Lexi Engelman" <jeffrey.engelman@novartis.com>, Scott Brown <scott.brown@novartis.com>, Revathi Rammohan <revathi.rammohan@novartis.com>
Subject: Re: PACT and Novartis

Hi Jay,

(b) (4)

(b) (4) Please le us know if there are any questions remaining to be answered and we will be happy to jump on the phone.

Regards,
David Wholley
Foundation for the NIH
Sent from my BlackBerry 10 smartphone.

From: Bradner, James
Sent: Sunday, September 10, 2017 9:55 AM
To: Collins, Francis (NIH/OD) [E]
Cc: Wholley, David (FNIH) [T]; Engelman, Jeffrey; Brown, Scott; Rammohan, Revathi
Subject: Re: PACT and Novartis

Thank you, Francis. (b) (4)

(b) (4)

(b) (4) Best -

Jay

--

Jay Bradner, M.D.
President | Novartis Institutes for BioMedical Research
james.bradner[at]novartis.com

From: "Collins, Francis (NIH/OD) [E]" (b) (6)
Date: Saturday, September 9, 2017 at 5:08 PM
To: James Bradner <james.bradner@novartis.com>
Cc: "Wholley, David (FNIH) [T]" <dwholley@fnih.org>
Subject: PACT and Novartis

Hi Jay,



Many thanks, Francis

From: Wholley, David (FNIH) [T]
Sent: Fri, 29 Sep 2017 14:31:32 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Adam, Stacey (FNIH) [T];Baker, Rebecca (NIH/OD) [E];Wolinetz, Carrie (NIH/OD) [E]
Subject: FW: PACT and Novartis

See below. Let's hope [redacted] (b) (4)

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Engelman, Jeffrey [mailto:jeffrey.engelman@novartis.com]
Sent: Friday, September 29, 2017 10:28 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Caulfield, Anita <anita.caulfield@novartis.com>
Subject: Re: PACT and Novartis

Hi David,

[redacted] (b) (4)

All the best,

Jeff

Sent from my iPhone

On Sep 29, 2017, at 10:08 PM, Wholley, David (FNIH) [T] <dwholley@fnih.org> wrote:

Hi Jeff:

[redacted] (b) (4) It would be great if you could find a way to do the same, and join the group at the announcement on the 12th. Let me know if there is anything I can do to help that process.

David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Engelman, Jeffrey [mailto:jeffrey.engelman@novartis.com]
Sent: Thursday, September 28, 2017 9:20 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Caulfield, Anita <anita.caulfield@novartis.com>
Subject: Re: PACT and Novartis

Hi David,

I hope all is well. As you know, we are very supportive [redacted] (b) (4)

[redacted] (b) (4)

All the best,

Jeff

Jeffrey Engelman, M.D., Ph.D.
Global Head of Oncology
Novartis Institutes for BioMedical Research

Executive Assistant: Anita Caulfield
anita.caulfield@novartis.com
(617)-871-8200

From: "Wholley, David (FNIH) [T]" <dwholley@fnih.org>
Date: Tuesday, September 26, 2017 at 5:40 PM
To: Jeffrey Engelman <jeffrey.engelman@novartis.com>
Cc: "Caulfield, Anita" <anita.caulfield@novartis.com>
Subject: FW: PACT and Novartis

Hi Jeff:

The announcement of the launch of the Partnership to Advance Cancer Therapies (PACT) is almost certainly going to be on October 12, at the National Press Club. I am being asked by the NIH communications team whom to include in the announcement and related press push, etc. It would be great to have a formal decision from Novartis on PACT as soon as possible. (b) (4) (b) (4)

Thanks,

David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Bradner, James [mailto:james.bradner@novartis.com]
Sent: Tuesday, September 19, 2017 3:23 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: Re: PACT and Novartis

thank you, david. i know that jeff is meeting with (b) (4) this week to discuss. thanks so much - jay

--

Jay Bradner, M.D.
President | Novartis Institutes for BioMedical Research
james.bradner[at]novartis.com

From: "Wholley, David (FNIH) [T]" <dwholley@fnih.org>
Date: Monday, September 11, 2017 at 3:48 AM
To: James Bradner <james.bradner@novartis.com>, "Collins, Francis (NIH/OD) [E]"
(b) (6)
Cc: "Jeff, Dana + Lexi Engelman" <jeffrey.engelman@novartis.com>, Scott Brown <scott.brown@novartis.com>, Revathi Rammohan <revathi.rammohan@novartis.com>
Subject: Re: PACT and Novartis

Hi Jay,

(b) (4)

(b) (4) Please le us know if there are any questions remaining to be answered and we will be happy to jump on the phone.

Regards,
David Wholley
Foundation for the NIH
Sent from my BlackBerry 10 smartphone.

From: Bradner, James
Sent: Sunday, September 10, 2017 9:55 AM
To: Collins, Francis (NIH/OD) [E]
Cc: Wholley, David (FNIH) [T]; Engelman, Jeffrey; Brown, Scott; Rammohan, Revathi
Subject: Re: PACT and Novartis

Thank you, Francis. I remain enthusiastic about PACT. (b) (4)

(b) (4)

(b) (4)
Best -

Jay

--

Jay Bradner, M.D.
President | Novartis Institutes for BioMedical Research
james.bradner[at]novartis.com

From: "Collins, Francis (NIH/OD) [E]" (b) (6)
Date: Saturday, September 9, 2017 at 5:08 PM
To: James Bradner <james.bradner@novartis.com>
Cc: "Wholley, David (FNIH) [T]" <dwholley@fnih.org>
Subject: PACT and Novartis

Hi Jay,

(b) (4)

Many thanks, Francis

From: Wholley, David (FNIH) [T]
Sent: Tue, 26 Sep 2017 14:15:52 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: FW: PACT follow-up

Here

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Wholley, David (FNIH) [T]
Sent: Tuesday, September 26, 2017 7:36 AM
To: (b) (4)>
Cc: (b) (4) Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Subject: Re: PACT follow-up

(b) (4)
(b) (4) David

Sent from my BlackBerry 10 smartphone.

From: (b) (4)
Sent: Monday, September 25, 2017 11:17 AM
To: Wholley, David (FNIH) [T]
Cc: Dracopoli, Nicholas [JRDUS]; Adam, Stacey (FNIH) [T]
Subject: RE: PACT follow-up

Hi David,

(b) (4)

From: Wholley, David (FNIH) [T] [mailto:dwholley@fnih.org]
Sent: Monday, September 18, 2017 5:10 PM
To: (b) (4)
Cc: (b) (4) Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Subject: RE: PACT follow-up

Peter:

(b) (4)

Regards,

David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Wholley, David (FNIH) [T]
Sent: Friday, September 15, 2017 2:00 PM
To: (b) (4)
Cc: (b) (4) Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Subject: PACT follow-up

(b) (4)

Regards,
David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Wholley, David (FNIH) [T]
Sent: Mon, 25 Sep 2017 16:07:54 +0000
To: Collins, Francis (NIH/OD) [E];Lowy, Douglas (NIH/NCI) [E];Doroshow, James (NIH/NCI) [E];Tabak, Lawrence (NIH/OD) [E];Wolinetz, Carrie (NIH/OD) [E]
Cc: Baker, Rebecca (NIH/OD) [E];Adam, Stacey (FNIH) [T]
Subject: FW: PACT follow-up

(b) (4)

[redacted]

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: (b) (4) [redacted]
Sent: Monday, September 25, 2017 11:16 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: (b) (4) [redacted] Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Subject: RE: PACT follow-up

Hi David,

(b) (4)

[redacted]

From: Wholley, David (FNIH) [T]
Sent: Wed, 27 Sep 2017 23:24:00 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Tabak, Lawrence (NIH/OD) [E];Baker, Rebecca (NIH/OD) [E];Lowy, Douglas (NIH/NCI) [E];Doroshow, James (NIH/NCI) [E];Wolinetz, Carrie (NIH/OD) [E]
Subject: Fw: PACT follow-up

Looks like your note to Paul did the trick. Congrats, need two more!
Sent from my BlackBerry 10 smartphone.

From: (b) (4)
Sent: Wednesday, September 27, 2017 7:10 PM
To: Wholley, David (FNIH) [T]
Cc: Adam, Stacey (FNIH) [T]
Subject: RE: PACT follow-up

(b) (4)

From: Wholley, David (FNIH) [T] [mailto:dwholley@fnih.org]
Sent: Tuesday, September 26, 2017 7:36 AM
To: (b) (4)
Cc: (b) (4) Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Subject: Re: PACT follow-up

(b) (4)

Sent from my BlackBerry 10 smartphone.

From: (b) (4)
Sent: Monday, September 25, 2017 11:17 AM
To: Wholley, David (FNIH) [T]
Cc: (b) (4) Adam, Stacey (FNIH) [T]
Subject: RE: PACT follow-up

Hi David,

(b) (4)

From: Wholley, David (FNIH) [T] [mailto:dwholley@fnih.org]
Sent: Monday, September 18, 2017 5:10 PM
To: (b) (4)
Cc: Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Subject: RE: PACT follow-up

(b) (4)

Regards,

David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Wholley, David (FNIH) [T]
Sent: Friday, September 15, 2017 2:00 PM
To: (b) (4)
Cc: Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Subject: PACT follow-up

(b) (4)

Regards,
David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343

fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Wholley, David (FNIH) [T]
Sent: Mon, 9 Oct 2017 17:57:40 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Myles, Renate (NIH/OD) [E]
Subject: FW: PACT Press Conference on Oct. 12 at 10:00 am ET

fyi

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Reese, David [mailto:dreese@amgen.com]
Sent: Monday, October 09, 2017 1:17 PM
To: Myles, Renate (NIH/OD) [E] (b) (6)
Cc: Harper, Sean <sharper@amgen.com>; Coffey, Eva <egroves@amgen.com>; Burklow, John (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Subject: Re: PACT Press Conference on Oct. 12 at 10:00 am ET

Renate,

Thanks for the invitation for the press conference. We will try to get a senior person from Amgen there on Thursday - will let you know shortly and once we receive the formal invitation.

Best regards,

Dave

David Reese, MD
Senior Vice President, Translational Sciences
Amgen Inc
+1 805-447-1612

On Oct 9, 2017, at 9:43 AM, Myles, Renate (NIH/OD) [E] (b) (6)> wrote:

Hi Drs. Harper and Reese:

David Wholley just shared the exciting news that Amgen will be joining PACT. I did want make you aware that we will be holding a press conference at the National Press Club on Thursday, Oct. 12 at

10:00 a.m. ET to launch this important new partnership. You will be receiving a formal invitation from Dr. Collins to join us. The NPC is located at 529 14th St. NW, Washington, D.C. We have reserved a green room for the entire day (Zenger Room) and will hold a "pre-event" meeting in this room at 9:15 a.m., with the press conference beginning promptly at 10:00 a.m. ET in the Fourth Estate Room.

We hope that an Amgen principal or an appropriate designee will be able to join the event. I will be sharing more specifics about the event tomorrow and will be in touch with Eva shortly about materials.

All the best,
Renate

Renate Myles, MBA
Acting Deputy Director
Office of Communications and Public Liaison
Chief, News Media Branch
National Institutes of Health
Tel (b) (6)
Email: (b) (6)